# TITLE PAGE

## INTERIM FULL CLINICAL STUDY REPORT

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| **CSR Title:** | Substudy A Interim Report – 6-Month Analysis: A Phase 3 Master Protocol to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2 |
| **Study Number:** | C4591031 |
| **Study Phase:** | Phase 3 |
| **Compound:** | PF-07302048 (BNT162b2) |
| **Trade Name:** | Comirnaty® |
| **Study Sponsor:** | BioNTech SE |
| **Sponsor Agent:** | Pfizer Inc. |
| **Sponsor's Signatory:** | Federico Mensa, MD<br>Vice President, Clinical Development, BioNTech SE |
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| **Study Initiation Date (FPFV):** | 01 July 2021 |
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| | Substudy A Interim CSR – 6 Month Analysis – Version 1.0 | 25 April 2022 |
| | Substudy A Interim CSR – 2 Month Analysis – Version 1.0 | 18 November 2021 |

**GOOD CLINICAL PRACTICE STATEMENT**

This study was conducted in compliance with GCP guidelines and, where applicable, local country regulations relevant to the use of new therapeutic agents in the country/countries of conduct, including the archiving of essential documents.

# SYNOPSIS

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## LIST OF ABBREVIATIONS AND DEFINITIONS OF TERMS

| Abbreviation | Definition |
|---|---|
| AE | adverse event |
| AESI | adverse event of special interest |
| BMI | body mass index |
| CDC | Centers for Disease Control and Prevention (United States) |
| CFR | Code of Federal Regulations |
| CIOMS | Council for International Organizations of Medical Sciences |
| COVID-19 | coronavirus disease 2019 |
| CPAP | continuous positive airway pressure |
| CRF | case report form |
| CRO | contract research organization |
| CSR | clinical study report |
| CT | computed tomography |
| DBP | diastolic blood pressure |
| DCT | data collection tools |
| EUA | emergency use authorization |
| Eudra CT | European Union Drug Regulating Authorities Clinical Trials Database |
| FDA | Food and Drug Administration |
| FPFV | first participant first visit |
| GCP | Good Clinical Practice |
| GI | gastrointestinal |
| HIV | human immunodeficiency virus |
| ICD | informed consent document |
| ICH | International Council of Harmonisation of Technical Requirements for Pharmaceuticals for Human Use |
| ICU | intensive care unit |
| IEC | independent ethics committee |
| IRB | institutional review board |
| IRR | illness rate ratio |
| IRT | interactive response technology |
| IWR | interactive Web-based response |
| LNP | lipid nanoparticle |
| MedDRA | Medical Dictionary for Regulatory Activities |
| MI | myocardial infarction |
| mITT | modified intent-to-treat |
| modRNA | nucleoside-modified messenger ribonucleic acid |
| MRI | magnetic resonance imaging |
| NAAT | nucleic acid amplification test |
| N-binding | SARS-CoV-2 nucleoprotein binding |
| NCT | national clinical trial |
| PACL | protocol administrative change letter |

| | |
|---|---|
| P2 S | SARS-CoV-2 full-length, P2 mutant, prefusion spike glycoprotein |
| PD | protocol deviation |
| PT | preferred term |
| QTL | quality tolerance limit |
| RNA | ribonucleic acid |
| RVE | relative vaccine efficacy |
| S | spike protein |
| SAE | serious adverse event |
| SAP | statistical analysis plan |
| SARS | severe acute respiratory syndrome |
| SARS-CoV-2 | severe acute respiratory syndrome coronavirus 2 |
| SBP | systolic blood pressure |
| $SpO_2$ | oxygen saturation as measured by pulse oximetry |
| SOC | system organ class |
| TEAE | treatment emergent adverse events |
| TME | targeted medical event |
| US | United States |
| USA | United States of America |
| VAED | vaccine-associated enhanced disease |
| VAERD | vaccine-associated enhanced respiratory disease |
| VE | vaccine efficacy |
| WHO | World Health Organization |

## ETHICS

### Independent Ethics Committee and/or Institutional Review Board

The protocol, protocol amendments, ICD, Investigator Brochure, and other relevant documents (eg, advertisements) were submitted to an IRB/IEC by the investigator and reviewed and approved by the IRB/IEC before the study was initiated. The IRBs/IECs are listed in Appendix 16.1.3.1.

Any amendments to the protocol required IRB/IEC approval before implementation of changes made to the study design, except for changes necessary to eliminate an immediate hazard to study participants.

### Ethical Conduct of the Study

This study was conducted in accordance with the protocol and consensus ethical principles derived from international guidelines including the Declaration of Helsinki Council and CIOMS International Ethical Guidelines, applicable ICH GCP Guidelines, and other applicable laws and regulations, including privacy laws.

### Participant Information and Consent

The investigator or his/her representative explained the nature of the study to the participant or his/her legally authorized representative and answered all questions regarding the study.

Participants or their legally authorized representative were informed that their participation was voluntary. Participants or their legally authorized representative signed a statement of informed consent that met the requirements of 21 CFR 50, local regulations, ICH guidelines, privacy and data protection requirements, where applicable, and the IRB/IEC or study center.

Investigative sites were instructed to obtain written informed consent before the participant was enrolled in the study and document the date the written consent was obtained. The authorized person obtaining the informed consent was also instructed to sign the ICD. Participants were reconsented to the most current version of the ICD(s) during their participation in the study.

A copy of the ICD(s) was provided to the participant or the participant's legally authorized representative.

## 1. INTRODUCTION

The global spread of the outbreak of COVID-19, caused by the SARS-CoV-2 virus, originating in Wuhan, China was characterized by the WHO as a pandemic in March 2020.[1] Pfizer and BioNTech have developed an RNA-based SARS-CoV-2 vaccine, BNT162b2, that is being investigated for the prevention of COVID-19 in individuals ≥6 months of age. A 2-dose series of BNT162b2 (given 21 days apart) has been granted a conditional marketing authorization, EUA, or temporary authorization in a total of more than 60 countries,[2,3,4] and has been fully licensed for use in individuals 16 years of age and above in the US as of 23 August 2021.[5] In the US, the FDA has issued EUAs for booster doses of BNT162b2 30 µg based on age and certain immune compromised conditions; this includes a first booster

dose, given at least 5 months after the second dose, for all individuals ≥12 years of age (as of 03 January 2022)[6] and a second booster dose, given at least 4 months after the first booster dose, for all individuals ≥50 years of age (as of 29 March 2022.[7] At present, with SARS-CoV-2 variants with multiple mutations in the S protein that might be associated with the lower efficacy of some of the approved/authorized vaccines, there is a need to continue research of new approaches, such as evaluation of booster doses, to overcome waning immunity and drive down levels of community transmission.

Phase 1/2/3 Study C4591001 is the registrational and pivotal study of the prophylactic BNT162b2 vaccine against COVID-19 in healthy individuals ≥12 years of age, that initiated in April 2020. In this study, a 2-dose series of BNT162b2 conferred an observed 95% protection against COVID-19 in persons 16 years of age or older after a median follow-up period of 2 months after the second dose.[8] However, as presented in April 2021, the observed efficacy of BNT162b2 from 7 days through up to 6 months after the second dose had decreased to 91.3% against COVID-19. However, the observed vaccine efficacy was 100% against severe disease as defined by the US CDC, and 95.3% against severe COVID-19 as defined by the US FDA.[9]

In the ongoing Phase 3 randomized, placebo-controlled, observer-blind Substudy A of C4591031, the safety, tolerability, and efficacy of a booster dose of BNT162b2 is being evaluated in participants ≥16 years of age from Study C4591001 at least 6 months after completing the 2-dose primary series in Study C4591001. Results from the first interim analysis at 2 months (interim CSR dated 18 November 2021) demonstrated that a booster dose administered to individuals who previously received a primary 2-dose series of BNT162b2 restored vaccine protection against COVID-19 to the high levels achieved after the second dose, showing an observed relative VE of 95.6% when compared to those who did not receive the booster.[10] Furthermore, the tolerability and safety profile of a booster dose of BNT162b2 30 µg at up to 2 months after booster vaccination (to the data cutoff date) was acceptable and consistent with results previously reported.

C4591031 Substudy A is part of the master protocol to evaluate BNT162b2 boosting strategies across different populations of participants (eg, age groups). This C4591031 6-month interim report for Substudy A includes the following analyses (based on a data cutoff date of 08 February 2022):

- Efficacy analyses of a single booster dose of BNT162b2 30 µg from 7 days after booster dose during the blinded placebo-controlled follow-up period (Section 5.1.1), and analysis of COVID-19 cases through the entire study follow-up period in participants who received BNT162b2 initially or subsequently after unblinding (Section 5.1.2).

- Safety analysis of a single booster dose of BNT162b2 30 µg as follows:

  - Blinded placebo-controlled follow-up period from booster vaccination to the unblinding date (Section 5.2.2.1.1);

  - Open-label follow-up period – original BNT162b2 recipients (Section 5.2.2.1.2);

- Blinded placebo-controlled and open-label follow-up periods from booster vaccination to 6 months after booster vaccination – original BNT162b2 participants with at least 6 months follow-up (Section 5.2.2.1.3);

- Open-label follow-up period – original placebo recipients who then received BNT162b2 after unblinding (Section 5.2.2.1.4).

Other objectives in Substudy A of Study C4591031 (Section 2) will be reported at a later time.

## 2. STUDY OBJECTIVES, ESTIMANDS, AND ENDPOINTS

**The objectives and endpoints presented in this interim report for Substudy A are per Protocol Amendment 7 and SAP Version 1.** These were the effective versions at the time of the data cutoff (08 February 2022) and data analyses included in this interim report. Refer to Section 3.1.2 and Section 3.7.2 for information regarding amendments to the protocol and SAP, respectively.

Study objectives and endpoint analyses that were either previously reported, or will be reported at a later time, are indicated with gray shading and per the 'reference' column in Table 1.

**Table 1. Objectives, Estimands, and Endpoints**

| Objectives | Estimands | Endpoints | Reference |
|---|---|---|---|
| **Primary Efficacy** | | | |
| To describe the efficacy of a booster dose of BNT162b2 against confirmed COVID-19 occurring from 7 days after the booster dose through the blinded follow-up period in participants without evidence of past SARS-CoV-2 infection | In participants complying with the key protocol criteria (evaluable participants) and with no serological or virological evidence (prior to 7 days after receipt of the booster dose) of past SARS-CoV-2 infection:<br><br>100 × (1 – IRR) [ratio of active vaccine to placebo] | Confirmed COVID-19 incidence from 7 days after the booster dose per 1000 person-years of blinded follow-up | Interim data for at least 2 months of follow-up after booster vaccination (to the date cutoff date of 05 October 2021) are reported in the 2-month analysis interim CSR dated 18 November 2021.<br><br>Updated efficacy data from 7 days after booster vaccination through the blinded follow-up period (to the data cutoff date of 08 February 2022) are reported in this CSR. |
| To describe the efficacy of a booster dose of BNT162b2 against confirmed COVID-19 occurring from 7 days after the booster dose through the blinded follow-up period in participants with and without evidence of past SARS-CoV-2 infection | In participants complying with the key protocol criteria (evaluable participants) with or without serological or virological evidence (prior to 7 days after receipt of the booster dose) of past SARS-CoV-2 infection: | Confirmed COVID-19 incidence from 7 days after the booster dose per 1000 person-years of blinded follow-up | Interim data for at least 2 months of follow-up after booster vaccination (to the date cutoff date of 05 October 2021) are reported in the 2-month analysis interim CSR |

## Table 1. Objectives, Estimands, and Endpoints

| Objectives | Estimands | Endpoints | Reference |
|---|---|---|---|
| | 100 × (1 – IRR) [ratio of active vaccine to placebo] | | dated 18 November 2021.<br><br>Updated efficacy data from 7 days after booster vaccination through the blinded follow-up period (to the data cutoff date of 08 February 2022) are reported in this CSR. |
| **Primary Safety** | | | |
| To define the safety profile of a booster dose of BNT162b2 | In participants receiving 1 dose of study intervention, the percentage of participants reporting:<br>• AEs from the booster dose to 1 month after the booster dose<br>• SAEs from the booster dose to 6 months after the booster dose | • AEs<br>• SAEs | Interim data reported up to 1 month after booster vaccination and to the data cutoff date of 05 October 2021 are reported in the 2-month analysis interim CSR dated 18 November 2021.<br><br>Interim data for AEs and SAEs reported up to 6 months after booster vaccination and to the data cutoff date of 08 February 2022 are reported in this CSR. |
| **Secondary Efficacy** | | | |
| To describe the efficacy of a booster dose of BNT162b2 against confirmed severe COVID-19 (based on FDA definition) occurring from 7 days after the booster dose through the blinded follow-up period in participants without evidence of past SARS-CoV-2 infection | In participants complying with the key protocol criteria (evaluable participants) and with no serological or virological evidence (prior to 7 days after receipt of the booster dose) of past SARS-CoV-2 infection:<br><br>100 × (1 – IRR) [ratio of active vaccine to placebo] | Confirmed severe COVID-19 (based on FDA definition) incidence from 7 days after the booster dose per 1000 person-years of blinded follow-up | Interim data for at least 2 months of follow-up after booster vaccination (to the data cutoff date of 05 October 2021) are reported in the 2-month analysis interim CSR dated 18 November 2021.<br><br>Updated efficacy data from 7 days after booster vaccination through the blinded follow-up period (to the data cutoff date of 08 February 2022) are reported in this CSR. |
| To describe the efficacy of a booster dose of BNT162b2 against confirmed severe COVID-19 (based on FDA definition) occurring from 7 days after the booster dose through the blinded follow-up period in participants | In participants complying with the key protocol criteria (evaluable participants) and with or without serological or virological evidence (prior to 7 days after receipt of the | Confirmed severe COVID-19 (based on FDA definition) incidence from 7 days after the booster dose per 1000 person-years of blinded follow-up | Interim data for at least 2 months of follow-up after booster vaccination (to the data cutoff date of 05 October 2021) are reported in the 2-month |

## Table 1. Objectives, Estimands, and Endpoints

| Objectives | Estimands | Endpoints | Reference |
|---|---|---|---|
| with and without evidence of past SARS-CoV-2 infection | booster dose) of past SARS-CoV-2 infection:<br><br>100 × (1 – IRR) [ratio of active vaccine to placebo] | | analysis interim CSR dated 18 November 2021.<br><br>Updated efficacy data from 7 days after booster vaccination through the blinded follow-up period (to the data cutoff date of 08 February 2022) are reported in this CSR. |
| To describe the efficacy of a booster dose of BNT162b2 against confirmed severe COVID-19 (based on CDC definition) occurring from 7 days after the booster dose through the blinded follow-up period in participants without evidence of past SARS-CoV-2 infection | In participants complying with the key protocol criteria (evaluable participants) and with no serological or virological evidence (prior to 7 days after receipt of the booster dose) of past SARS-CoV-2 infection:<br><br>100 × (1 – IRR) [ratio of active vaccine to placebo] | Confirmed severe COVID-19 (based on CDC definition) incidence from 7 days after the booster dose per 1000 person-years of blinded follow-up | Interim data for at least 2 months of follow-up after booster vaccination (to the data cutoff date of 05 October 2021) are reported in the 2-month analysis interim CSR dated 18 November 2021.<br><br>Updated efficacy data from 7 days after booster vaccination through the blinded follow-up period (to the data cutoff date of 08 February 2022) are reported in this CSR. |
| To describe the efficacy of a booster dose of BNT162b2 against confirmed severe COVID-19 (based on CDC definition) occurring from 7 days after the booster dose through the blinded follow-up period in participants with and without evidence of past SARS-CoV-2 infection | In participants complying with the key protocol criteria (evaluable participants) and with or without serological or virological evidence (prior to 7 days after receipt of the booster dose) of past SARS-CoV-2 infection:<br><br>100 × (1 – IRR) [ratio of active vaccine to placebo] | Confirmed severe COVID-19 (based on CDC definition) incidence from 7 days after the booster dose per 1000 person-years of blinded follow-up | Interim data for at least 2 months of follow-up after booster vaccination (to the data cutoff date of 05 October 2021) are reported in the 2-month analysis interim CSR dated 18 November 2021.<br><br>Updated efficacy data from 7 days after booster vaccination through the blinded follow-up period (to the data cutoff date of 08 February 2022) are reported in this CSR. |

**Table 1. Objectives, Estimands, and Endpoints**

| Objectives | Estimands | Endpoints | Reference |
|---|---|---|---|
| To describe the efficacy of a booster dose of BNT162b2 against asymptomatic infection in participants without evidence of past SARS-CoV-2 infection | In complying with the key protocol criteria (evaluable participants) and with no serological or virological evidence of past SARS-CoV-2 infection:<br>100 × (1 – IRR) [ratio of active vaccine to placebo] | Incidence of asymptomatic SARS-CoV-2 infection per 1000 person-years of follow-up based on N-binding antibody seroconversion | Data will be reported at a later time. |
| **Exploratory** | | | |
| To describe the incidence of confirmed COVID-19 through the entire study follow-up period in participants who received the BNT162b2 booster dose | In participants who received BNT162b2 at the booster vaccination (at initial randomization or subsequently):<br><br>Incidence per 1000 person-years of follow-up | Confirmed COVID-19 incidence per 1000 person-years of follow-up | Interim data for at least 6 months of follow-up after booster vaccination (to the data cutoff date of 08 February 2022) for participants originally randomized to BNT162b2 and for participants originally randomized to placebo who were then unblinded and received BNT162b2 with various length of follow-up are reported in this CSR.<br><br>Updated data for the entire study follow-up period will be reported at a later time. |

Source: Appendix 16.1.1, Protocol Section 10.7.3

## 3. INVESTIGATIONAL PLAN

**The objectives and endpoints presented in this interim report for Substudy A are per Protocol Amendment 7 and SAP Version 1.** These were the effective versions at the time of the data cutoff (08 February 2022) and data analyses included in this interim report. Refer to Section 3.1.2 and Section 3.7.2 for information regarding amendments to the protocol and SAP, respectively.

### 3.1. Overview of Study Design

This is a Phase 3 randomized, placebo-controlled, observer-blind substudy to evaluate the safety, tolerability, and efficacy of a booster dose of BNT162b2 30 µg. Participants ≥16 years of age from the pivotal Study C4591001 who completed a 2-dose primary series of BNT162b2 at least 6 months prior to randomization were enrolled, and approximately 10,000 participants were to be randomized at a ratio of 1:1 to receive either BNT162b2 or placebo. Randomization was stratified by age, such that approximately 60% of participants enrolled would be ≥16 to 55 years of age and approximately 40% of participants >55 years of age.

Participants who were randomized to receive placebo at the booster vaccination visit were offered the opportunity to receive BNT162b2 if indicated by the outcome of the interim analyses, or at the discretion of the study sponsor agent (Section 3.1.1).

### 3.1.1. Discussion of Study Design

In Substudy A of the C4591031 master protocol, interim efficacy analyses were originally planned to be performed every 2 months by an unblinded statistical team to inform the timing of unblinding and administration of BNT162b2 to those originally assigned to placebo (Appendix 16.1.1, Protocol Section 10.7.9.4). However, on 22 September 2021, the US FDA issued an EUA for a booster dose of BNT162b2 for individuals 65 years of age and older, individuals 18 through 64 years of age at high risk of severe COVID-19, and individuals 18 through 64 years of age whose frequent institutional or occupational exposure to SARS-CoV-2 puts them at high risk of serious complications of COVID-19, including severe COVID-19. Based on sponsor discretion as outlined in the C4591031 protocol, from 24 September 2021, all C4591031 Substudy A participants were eligible to be unblinded, and all placebo recipients could choose to receive a booster dose of BNT162b2 30 µg as part of the substudy. The timing of this was just prior to the pre-planned analysis after 2 months of follow-up.

After study participants were eligible for unblinding, and completion of the first interim analysis, follow-up interim analyses every 2 months were no longer applicable. The efficacy and safety analyses presented in this 6-month analysis CSR were conducted using complete blinded follow-up period data with supportive analyses using data during blinded and open-label follow-up periods (refer to Section 3.7.2).

The study is observer-blinded, as the physical appearance of the investigational vaccine candidates and the placebo differ, and participants received 1 dose of study intervention at Visit 1 by an unblinded administrator. For participants who were randomized to receive placebo at the booster vaccination visit, administration of BNT162b2 at Visit 101 was conducted in an open-label manner. Refer to Section 4.1 for further details of the number of participants who were unblinded and the timing of unblinding.

The BNT162b2 dose of 30 µg was selected for C4591001 Phase 2/3 of evaluation of safety, immunogenicity, and efficacy. A placebo was used as the control, as there is no licensed comparator vaccine available.

Refer to Appendix 16.1.1, Protocol Section 2.1 for the study rationale, including studying boosting strategies under a single master protocol.

### 3.1.2. Changes in Study Conduct

All changes in the conduct of all C4591031 substudies were implemented by amendments to the master protocol, as described in Appendix 16.1.1, Protocol Section 10.13 and the Document History. All PACLs issued were incorporated into the subsequent protocol amendment.

**Protocol Amendment 7 (17 February 2022) was the effective protocol version at the time of the data cutoff and data analyses included in this interim report.**

Protocol Amendment 8 was approved on 31 March 2022, and changes were primarily related to other substudies. For Substudy A, Protocol Amendment 8 added language to permit early discontinuation of participants in Substudy A for reasons including (but not limited to) access and availability of BNT162 in the real world, reducing the needed for participant involvement and observation in this clinical trial.

### 3.2. Investigators and Study Administrative Structure

The study was undertaken by Pfizer Inc. and BioNTech SE (the sponsor) and conducted by investigators contracted by and under the direction of Pfizer. The investigators were responsible for adhering to the study procedures described in the protocol, for keeping records of study intervention, and for accurately completing and signing the CRFs/DCTs supplied by the sponsor agent. A list of investigators and sites (including participants by country), and service providers involved in this study is available in Appendix 16.1.4.

As of the data cutoff date of 08 February 2022, no sites were terminated from Substudy A.

### 3.3. Selection of Study Population

#### 3.3.1. Inclusion/Exclusion Criteria

Participants must have met all of the general inclusion and exclusion criteria as specified for the master protocol (Appendix 16.1.1, Protocol Section 5) and the Substudy A-specific criteria (Appendix 16.1.1, Protocol Section 10.7.5). Briefly, enrolled in this study were healthy participants ≥16 years of age who participated in C4591001 and received 2 prior doses of 30 µg BNT162b2 19-42 days apart, with the second dose being at least 175 days before Visit 1 (Day 1) in Study C4591031.

#### 3.3.2. Removal of Participants From Intervention or Study

The specific criteria and procedures for early discontinuation from study intervention(s) or withdrawal from the study are described in Appendix 16.1.1, Protocol Section 7.

### 3.4. Study Intervention

#### 3.4.1. Study Interventions Administered

The Study C4591001 vaccine candidate selected for Phase 2/3 evaluation was BNT162b2 at a dose of 30 µg. Study C4591031 Substudy A evaluated a third dose of BNT162b2 30 µg in participants who completed the 2-dose primary series of BNT162b2 at least 6 months prior to randomization in C4591031. Details of the study interventions, administered intramuscularly, are provided below:

- BNT162b2 (BNT162 RNA-LNP vaccine utilizing modRNA and encoding the P2 S): 30 µg
- Normal saline (0.9% sodium chloride solution for injection)

The manufacturing lot numbers for the study intervention(s) administered in this study are provided in Table 2. Appendix 16.1.6 provides a listing of participants receiving study

intervention(s) from specific batches, where more than 1 batch was used. The justification for the dose selected is described in Appendix 16.1.1, Protocol Section 4.3.

**Table 2. Investigational Product Lot Numbers – Substudy A Interim – 6-Month Analysis**

| Investigational Product | Manufacturer | Vendor Lot Number (Manufacturer) | Lot Number[a] (Pfizer) |
|---|---|---|---|
| BNT162b2 (30 µg) | BioNTech | ER5832 | PA2094601/P223937-0002L |
| | | ER5832 | PA2094601/P223937-0005L |
| | | ER5832 | PA2094601/P223937-0006L |
| Placebo (normal saline 0.9% sodium chloride solution) | Pfizer | DK2074;20-002221 | PA2069407/P223937-0001L |
| | | DK2074;20-002221 | PA2069407/P223937-0003L |
| | | DK2074;20-002957 | PA2073218/P223937-0007L |
| Diluent (normal saline 0.9% sodium chloride solution) | Pfizer | EE4253 | PA2091593/P223937-0004L |
| | | EE4253 | PA2091593/P223937-0008L |
| | | DK2074 | 20-002957/20-002957 |
| | | EG6817 | 21-AE-00141/21-AE-00141 |
| | | EE4253 | 21-AE-00075/21-AE-00075 |
| | | FG8096 | 21-AE-00325/21-AE-00325 |

Note: C4591031 End of Study Information and Quality Control (QC) Record for Study Drug Appendix (Section D) dated 15Apr2022 was used to create this table.
a. Lot number assigned to the investigational product by Pfizer Global Clinical Supply.
Protocol C4591031 Investigational Product Lot Numbers Table – Substudy A Interim – 6-Month Analysis, Final, Version 2.0, 18Apr2022.

### 3.4.2. Measures to Minimize Bias

#### Allocation

All participants were centrally assigned to randomized study intervention using an IRT system (IWR). The method used to assign/allocate participants is further described in Appendix 16.1.1, Protocol Section 6.3.1.

#### Blinding

In this observed-blinded study, the study staff receiving, storing, dispensing, preparing, and administering the study interventions were unblinded. All other study and site personnel, including the investigator, investigator staff, and participants, were blinded to study intervention assignments. In particular, the individuals who evaluate participant safety were blinded. At the BNT162b2 vaccination (Visit 101), the participants' study intervention assignments were unblinded if the information was not already available and the participants were thereafter followed in an open-label manner (Section 3.1.1).

The majority of sponsor and Pfizer staff were blinded to study intervention allocation. All laboratory testing personnel performing serology assays remain blinded to study intervention assigned/received throughout the study.

Substudy A would be unblinded to site personnel and all sponsor and Pfizer staff at a time informed by the outcome of the interim analyses, as detailed in Appendix 16.1.1, Protocol Section 10.7.9.4, or at a time decided by the sponsor agent. As discussed in Section 3.1.1, individual participants who were eligible for a booster dose in their country could be unblinded from 24 September 2021 onwards. The efficacy and safety analyses presented in this CSR were conducted using complete blinded follow-up period data with supportive analyses using data during blinded and open-label follow-up periods (refer to Section 3.7.2).

Refer to Appendix 16.1.1, Protocol Section 10.7.6.2.1 for details on blinding of the site personnel, Protocol Section 10.7.6.2.2 for details on blinding of sponsor and Pfizer staff, and Protocol Section 10.7.6.2.3 for circumstances when the blind could be broken.

### 3.4.3. Study Intervention Compliance

Participants vaccinated at the site received study intervention directly from the investigator or designee, under medical supervision.

Refer to Appendix 16.1.1, Protocol Section 6.4 for details of compliance with study intervention.

### 3.4.4. Prior, Concomitant, and Post-Intervention Therapy

The medications and vaccinations allowed or disallowed in the study, including any exceptions to these requirements, are described in Appendix 16.1.1, Protocol Section 6.8.

## 3.5. Study Assessments and Procedures

### 3.5.1. Planned Measurements and Timing of Assessments

The specific efficacy and safety assessments and the schedule and measurement/collection methods are provided in the Schedule of Activities (Appendix 16.1.1, Protocol Section 10.7.1.3) and described in the protocol (Appendix 16.1.1, Protocol Sections 8.1, 8.2, and 10.7.8).

**Efficacy**

Efficacy was assessed throughout a participant's involvement in the study through surveillance for potential cases of COVID-19. If, at any time, a participant developed acute respiratory illness, for the purposes of the study he or she was considered to potentially have COVID-19 illness.[11] The assessments included a nasal (midturbinate) swab, which was tested at a central laboratory using an approved and validated RT-PCR test, or other equivalent nucleic acid amplification–based test (ie, NAAT) to detect SARS-CoV-2. In addition, clinical information and results from local standard-of-care tests were assessed. The central laboratory NAAT result was used for the case definition, unless no result was available from the central laboratory, in which case a local NAAT result could be used. Refer to Appendix 16.1.1, Protocol Section 10.7.8.1.1 for further details, including definitions of SARS-CoV-2-related cases and SARS-CoV-2-related severe cases (per FDA[12] and CDC[13]) and which assays must be used for results from local laboratories.

**Safety**

The collection and assessment of safety information during the study (evaluation, definitions, recording, and reporting of AEs, SAEs, AESIs and other reportable safety events) is detailed in Appendix 16.1.1, Protocol Section 8.3. Acute reactions within the first 30 minutes after administration of the study intervention were recorded as immediate AEs.

AEs of myocarditis and pericarditis were collected as AESIs. Potential COVID-19 illnesses and their sequelae that were consistent with the clinical endpoint definition were not recorded as AEs or considered AESIs, and were not typically reported according to the standard process for expedited reporting of SAEs (refer to Appendix 16.1.1, Protocol Section 8.3.7.1 for exceptions).

Additionally, Pfizer utilized a list of TMEs of specific clinical interest that are highlighted during clinical safety data review and signal detection. TMEs are a dynamic list of MedDRA AE terms that are reviewed on an ongoing basis throughout the clinical study; the TMEs are selected based on review of known pharmacology, toxicology findings, possible class effects, published literature, and potential signals arising from safety data assessments. The TME list includes events of interest due to their association with COVID-19 and terms of interest for vaccines in general; it takes into consideration the CDC list of AESIs for COVID-19.

### 3.5.2. Appropriateness of Measures

The efficacy and safety estimands and endpoints used in this study were consistent with those for prior BNT162b2 studies (C4591001, C4591007), considered to be reliable, and relevant to the objectives set forth in the protocol (Appendix 16.1.1, Protocol Section 3).

## 3.6. Data Quality Assurance

The sections below summarize the steps taken to ensure quality of the data included in this interim CSR with a data cutoff date of 08 February 2022.

### 3.6.1. Study Monitoring

Study centers were monitored by ICON. Centers were visited (virtually or in-person) at regular intervals and a Visit Log was maintained. Monitors were responsible for reviewing adherence to the protocol; compliance with GCP; and the completeness, accuracy, and consistency of the data. Direct access to participant medical and laboratory records was permitted to verify entries on the study-specific CRFs.

### 3.6.2. Investigator Meetings and Staff Training

Investigator staff training was provided by Pfizer and ICON during the investigator meeting, site initiation visit, and routine monitoring visits. The sponsor agent organized investigator and clinical research associate meetings before study start and during the study to provide information on the study intervention, the study rationale and design, responsibilities under ICH/FDA/GCP, and training on the detailed study requirements.

### 3.6.3. Laboratory Procedures

A central laboratory was used to analyze the samples (eg, nasal swab) to test for COVID-19 (Appendix 16.1.10/Module 5.3.1.4). Local laboratories could be used only if performed with the assays specified in Appendix 16.1.1, Protocol Section 10.7.8.1.1.

### 3.6.4. Investigator Responsibilities

The investigators were responsible for all data entered in the CRF and documented their review and approval of the data, verifying the validity and completeness of the data. The investigators were responsible for appropriate retention of essential study documents.

### 3.6.5. Clinical Data Management

CRF data were captured via data entry by study center personnel in a sponsor agent database system. Data quality checks were applied using both manual and electronic verification methods. An audit trail was maintained to support data query resolution and any modification to the data.

### 3.6.6. Clinical Quality Assurance Audits

Audits of this study were included as part of the independent sponsor agent quality assessment performed by Pfizer's own independent quality assurance group or by a CRO and/or individual contract personnel under the group's direction. The audit certificates for this study are provided in Appendix 16.1.8.

### 3.6.7. Quality Tolerance Limits

The quality management approach used in this study identified risks significant to human participant protection or reliability of trial results. The quality risk management plan used in this study documents risks and controls that are in place throughout the life of the study. In this study, QTLs were defined during the quality risk management planning.

Throughout the study up to the data cutoff date, the QTLs were routinely assessed and no important deviations were observed.

## 3.7. Statistical Analysis

### 3.7.1. Statistical Analysis Plan

The efficacy and safety analysis methods are described briefly here. Further details for the statistical analyses and methods, analysis populations, and determination of sample size are available in the protocol (Appendix 16.1.1, Protocol Sections 9.3 and 10.7.9) and SAP (Appendix 16.1.9, SAP Sections 4, 5, and 6).

#### General Considerations

The evaluable efficacy population was the primary analysis population for all efficacy analyses. Additional analyses based on the all-available efficacy (mITT) population were performed. The safety analyses were based on the safety population. Participants were

summarized by vaccine group as administered. Missing AE dates were handled according to the Pfizer safety rules; missing laboratory results were not imputed.

All objectives in this substudy were descriptive. No hypothesis testing was planned and no multiplicity adjustment was applied.

**Determination of Sample Size**

The study sample size of approximately 10,000 participants (randomized in a 1:1 ratio to receive BNT162b2 booster or placebo) was determined to accrue sufficient COVID-19 cases for the VE assessment, as described in Appendix 16.1.1, Protocol Section 10.7.9.5.

**Efficacy**

VE estimations, including for confirmed COVID-19 and the definitions of confirmed severe COVID-19 per the FDA[12] and CDC,[13] are described in the efficacy objectives, estimands, and endpoints presented in Table 1. The primary estimand defined for this substudy was RVE of the BNT162b2 booster group to the nonbooster group (placebo) during the blinded follow-up period; it was estimated in participants without prior evidence of SARS-CoV-2 infection before or during the vaccine or booster vaccine regimen, and those with or without prior evidence of SARS-CoV-2 infection. All participants had previously received the primary series of BNT162b2 30 µg, therefore RVE compares a third dose of active vaccine versus placebo. The associated 2-sided 95% CI for RVE was calculated using the Clopper-Pearson method adjusting for surveillance time.

Subgroup analyses of RVE were conducted based on demographics (age group, sex, race, and ethnicity), country, dose interval between Dose 2 and booster dose, baseline SARS-CoV-2 status, and risk status based on Charlson Comorbidity Index or a BMI ≥30 kg/m$^2$.

The IRs of confirmed COVID-19 illness during blinded and open-label follow-up periods for participants who received BNT162b2 at initial randomization and for those who received BNT162b2 subsequently after unblinding were summarized with 2-sided 95% CIs based on Poisson distribution.

**Safety**

The primary safety objective was evaluated for each vaccine group by descriptive summary statistics for AEs/SAEs (Table 1). (Note that reactogenicity events were recorded as AEs; no e-diary was used in this substudy for reactogenicity.) For safety analyses, count, percentages and the associated Clopper-Pearson 2-sided 95% CIs were provided. IRs accounted for differential follow-up time and the associated 2-sided 95% CI were also provided.

### 3.7.2. Changes in Planned Analyses Prior to Unblinding or Database Lock

For C4591031 Substudy A SAP, no changes were made to the planned analyses in SAP Version 1.

Supportive analyses were performed for COVID-19 cases accrued when the Delta variant was the predominant strain (ie, during a defined time period beginning 27 September 2021 [first placebo crossover participant to receive BNT162b2 vaccination] through 19 December 2021) and when the Omicron variant was the predominant strain (ie, during a defined time period beginning 20 December 2021 through the data cutoff date of 08 February 2022). These analyses are presented in Section 5.1.2.

## 4. STUDY PARTICIPANTS

Substudy A was conducted at 123 sites: US (117), South Africa (4), and Brazil (2) (Appendix 16.1.4.1).

For 1 participant (randomized to placebo), due to an erroneous entry of the end of study follow up completion, data points after that date were not included in the analyses for this interim report. Refer to the Errata for further details.

### 4.1. Disposition of Participants

**Blinded Placebo-Controlled Follow-Up Period**

During the blinded placebo-controlled follow-up period, most participants (99.0%) completed the 1-month telephone contact (Table 3). Few participants in the BNT162b2 (0.6%) and placebo (1.9%) groups withdrew from the study; across groups, the most commonly cited reason was withdrawal by the participant (0.7%).

**Open-Label Follow-Up Period**

Participants who were randomized to receive placebo at the booster vaccination visit were offered the opportunity to receive BNT162b2 if indicated by the outcome of the interim analyses or at the discretion of the study sponsor agent, and the participants' study intervention assignments were unblinded if the information was not already available and the participants were thereafter followed in an open-label manner (Section 3.1; Section 3.1.1).

Few participants (3.6%) who were originally randomized to BNT162b2 withdrew from the study during the open-label period (Table 3). The most common (2.0%) reason cited was "other," which was mostly due to participants enrolling in C4591031 Substudy D (Appendix 16.2.1).

Most participants (87.6%) originally randomized to the placebo group received a booster dose of BNT162b2 30 µg. Few participants (6.6%) were withdrawn from the study after unblinding and before a booster dose of BNT162b2. Of the participants in this group who received a booster dose of BNT162b2, few participants (4.7%) were withdrawn from the study; the most common (4.3%) reason cited was "other," which was mostly due to participants enrolling in C4591031 Substudy D (Appendix 16.2.1).

During the open label period, for participants who were originally randomized to BNT162b2 the frequency of withdrawal was 5.2% in the younger age group (16 to 55 years of age) and 1.7% in the older age group (>55 years of age). For participants who were originally randomized to placebo and received a booster dose of BNT162b2, the frequency of

withdrawal after unblinding was 8.1% in the younger age group and 0.4% in the older age group.

**Participants Not Known to be HIV-Positive**

The disposition of HIV-positive participants (50) is included in the summary of all randomized participants (10,136) but summarized separately in safety analyses. The disposition of the 10,086 participants randomized who were not known to be HIV-positive were similar to the overall study population.

**Table 3. Disposition of All Randomized Participants**

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5088) n[b] (%) | Placebo (N[a]=5048) n[b] (%) | Total (N[a]=10136) n[b] (%) |
| Randomized | 5088 (100.0) | 5048 (100.0) | 10136 (100.0) |
| Not vaccinated with booster dose | 6 (0.1) | 5 (0.1) | 11 (0.1) |
| Blinded follow-up period | | | |
| Vaccinated with booster dose | 5082 (99.9) | 5043 (99.9) | 10125 (99.9) |
| Completed the 1-month telephone contact | 5067 (99.6) | 4967 (98.4) | 10034 (99.0) |
| Withdrawn from the study | 29 (0.6) | 94 (1.9) | 123 (1.2) |
| Withdrawn after booster vaccination and before the 1-month telephone contact | 8 (0.2) | 26 (0.5) | 34 (0.3) |
| Withdrawn after the 1-month telephone contact | 21 (0.4) | 68 (1.3) | 89 (0.9) |
| Reason for withdrawal from the study | | | |
| Withdrawal by participant | 10 (0.2) | 59 (1.2) | 69 (0.7) |
| Lost to follow-up | 14 (0.3) | 19 (0.4) | 33 (0.3) |
| Protocol deviation | 0 | 5 (0.1) | 5 (0.0) |
| No longer meets eligibility criteria | 1 (0.0) | 3 (0.1) | 4 (0.0) |
| Death | 0 | 2 (0.0) | 2 (0.0) |
| Adverse event | 0 | 1 (0.0) | 1 (0.0) |
| Physician decision | 1 (0.0) | 0 | 1 (0.0) |
| Other | 3 (0.1) | 5 (0.1) | 8 (0.1) |
| Open-label follow-up period | | | |
| Unblinded after booster vaccination and before or on the same day of the 1-month telephone contact | 7 (0.1) | 50 (1.0) | 57 (0.6) |
| Unblinded after the 1-month telephone contact | 4498 (88.4) | 4852 (96.1) | 9350 (92.2) |
| Originally randomized to BNT162b2 | 4505 (88.5) | | |
| Completed the 1-month telephone contact | 6 (0.1) | | |
| Completed the 6-month visit | 3992 (78.5) | | |
| Withdrawn from the study | 185 (3.6) | | |
| Withdrawn before the 6-month visit | 142 (2.8) | | |

## Table 3. Disposition of All Randomized Participants

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5088) n[b] (%) | Placebo (N[a]=5048) n[b] (%) | Total (N[a]=10136) n[b] (%) |
| Withdrawn after the 6-month visit | 43 (0.8) | | |
| Reason for withdrawal from the study | | | |
| Withdrawal by participant | 30 (0.6) | | |
| Protocol deviation | 27 (0.5) | | |
| No longer meets eligibility criteria | 11 (0.2) | | |
| Lost to follow-up | 9 (0.2) | | |
| Death | 3 (0.1) | | |
| Withdrawal by parent/guardian | 2 (0.0) | | |
| Other | 103 (2.0) | | |
| Originally randomized to placebo | | 4902 (97.1) | |
| Withdrawn from the study after unblinding and before BNT162b2 vaccination | | 334 (6.6) | |
| Vaccinated with the booster dose (BNT162b2 [30 µg])[c] | | 4420 (87.6) | |
| Completed the 1-month telephone contact after BNT162b2 vaccination[c] | | 4366 (86.5) | |
| Withdrawn from the study | | 238 (4.7) | |
| Withdrawn after BNT162b2 vaccination and before the 1-month telephone contact | | 7 (0.1) | |
| Withdrawn after the 1-month telephone contact | | 231 (4.6) | |
| Reason for withdrawal from the study | | | |
| Withdrawal by participant | | 8 (0.2) | |
| Death | | 4 (0.1) | |
| Lost to follow-up | | 4 (0.1) | |
| No longer meets eligibility criteria | | 2 (0.0) | |
| Protocol deviation | | 1 (0.0) | |
| Other | | 219 (4.3) | |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
Note: Blinded follow-up period was censored to the cutoff date or the day before date of unblinding (per protocol) or the day before date of receiving COVID-19 vaccine off study, whichever date was earlier.
a. N = number of randomized participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Include one subject whose vaccine (as administered) could not be determined.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:12) Source Data: adds Table Generation: 14MAR2022 (10:43)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adds_s002_all_rand

Additional data are presented in the following:

| | |
|---|---|
| Disposition of All Randomized Participants, by Age Group | Supplemental Tables 14.1-14.2 |
| Disposition – Participants Not Known to be HIV-Positive | Supplemental Table 14.3 |

## 4.2. Important Protocol Deviations

Appendix 16.2.2 lists important protocol deviations that may significantly impact the completeness, accuracy, and/or reliability of the study data or that may significantly affect a participant's rights, safety, or well-being.

A formal acknowledgment by the study team was made that deviations were reviewed and GCP compliance was maintained.

Details of important PDs with the potential to impact the statistical analysis populations or to impact the assessment of safety of the participants are discussed below.

Across vaccine groups, the most commonly reported (3.0% total) type of important PD was related to receipt of other nonstudy coronavirus vaccine at any time during the study, which was reported in 0.8% of BNT162b2 participants and 2.2% of placebo participants (Supplemental Table 14.4). The next most commonly reported (1.2% total) important PD was related to the inclusion criteria requirement for receipt of the 2-dose series of BNT162b2 30 µg given 19-42 days apart, with the second dose being at least 175 days before booster study Visit 1 (Day 1).

## 4.3. Vaccine Administration and Timing

Almost all participants were administered booster vaccination as randomized; 99.9% received BNT162b2 30 µg in the BNT162b2 group, and 99.9% received placebo in the placebo group (Table 4). One (1) participant randomized to the BNT162b2 group received placebo (Appendix 16.2.5.1).

After unblinding, 87.5% of participants originally randomized to placebo received a booster vaccination of BNT162b2 30 µg by the time of the data cutoff date. For 1 participant, the vaccine (as administered) could not be determined (Appendix 16.2.7.3); this participant was not included in the analyses of open-label follow-up period – original placebo recipients who received BNT162b2 after unblinding.

During the blinded follow-up period, the time between Dose 2 of BNT162b2 (in Study C4591001) to booster vaccination was ≥10 to <12 months for the majority of participants (65.3% for both groups) (Table 5). The booster dose was received <6 months after Dose 2 (which was a protocol deviation) by ≤0.3% of participants in either group.

After unblinding of original placebo participants, the median time between Dose 2 (in Study C4591001) to open-label booster vaccination was 13.9 months.

## Table 4. Vaccine as Administered by Vaccine Group – All Randomized Participants

| Vaccine (as Administered) | Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=5088) n[b] (%) | Vaccine Group (as Randomized) Placebo (N[a]=5048) n[b] (%) |
|---|---|---|
| Vaccinated | 5082 (99.9) | 5043 (99.9) |
| Not vaccinated | 6 (0.1) | 5 (0.1) |
| Booster vaccination | | |
| BNT162b2 (30 µg) | 5081 (99.9) | 0 |
| Placebo | 1 (0.0) | 5043 (99.9) |
| Open-label booster vaccination | | |
| BNT162b2 (30 µg) | | 4419 (87.5) |
| Indeterminate vaccine[c] | | 1 (0.0) |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. "Indeterminate vaccine" refers to subjects whose vaccine (as administered) could not be determined.
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(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/advx_s002_adm_rand

## Table 5. Vaccine Administration Timing – All Randomized Participants

| | Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=5088) n[b] (%) | Vaccine Group (as Randomized) Placebo (N[a]=5048) n[b] (%) |
|---|---|---|
| Randomized | 5088 (100.0) | 5048 (100.0) |
| Not vaccinated | 6 (0.1) | 5 (0.1) |
| Blinded follow-up period | | |
| Received booster vaccination | 5082 (99.9) | 5043 (99.9) |
| Time from Dose 2 of BNT162b2 (in Study C4591001) to booster vaccination[c] | | |
| <6 Months | 14 (0.3) | 6 (0.1) |
| ≥6 Months to <8 months | 752 (14.8) | 732 (14.5) |
| ≥8 Months to <10 months | 819 (16.1) | 833 (16.5) |
| ≥10 Months to <12 months | 3320 (65.3) | 3298 (65.3) |
| ≥12 Months to <14 months | 176 (3.5) | 174 (3.4) |
| Mean (SD) | 10.1 (1.62) | 10.2 (1.59) |

**Table 5. Vaccine Administration Timing – All Randomized Participants**

| | Vaccine Group (as Randomized) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5088) n[b] (%) | Placebo (N[a]=5048) n[b] (%) |
| Median | 10.8 | 10.7 |
| Min, max | (5.0, 12.6) | (5.0, 12.8) |
| Open-label period | | |
| Received open-label booster vaccination | | 4420 (87.6) |
| Time from Dose 2 of BNT162b2 (in Study C4591001) to open-label booster vaccination[c] | | |
| ≥6 Months to <8 months | | 1 (0.0) |
| ≥8 Months to <10 months | | 429 (8.5) |
| ≥10 Months to <12 months | | 295 (5.8) |
| ≥12 Months to <14 months | | 1612 (31.9) |
| ≥14 Months to <16 months | | 1932 (38.3) |
| ≥16 Months to <18 months | | 146 (2.9) |
| ≥18 Months | | 5 (0.1) |
| Mean (SD) | | 13.5 (1.82) |
| Median | | 13.9 |
| Min, max | | (7.8, 18.3) |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. First and second doses of BNT162b2 (30 µg) were received in Study C4591001.
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(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/advx_s002_time_rand

## 4.4. Populations Analyzed

### 4.4.1. Safety Population

The safety population included a total of 10,125 participants: 5081 in the BNT162b2 group and 5044 in the placebo group (Table 6, Appendix 16.2.3.2). Of the 11 (0.1%) participants excluded from the safety population, all were excluded because they did not receive study intervention.

A total of 50 (0.5%) participants in the safety population had confirmed stable HIV disease, including 26 in the BNT162b2 group and 24 in the placebo group (Table 6). HIV-positive participants were included in this safety population summary and their safety data were analyzed separately.

The safety population included 5620 participants in the younger (16 to 55 years) group and 4505 participants in the older (>55 years) group (Supplemental Table 14.5). The younger and

older adult groups showed a balance between the BNT162b2 and placebo booster groups similar to the overall safety population.

**Table 6. Safety Population**

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) n[a] | Placebo n[a] | Total n[a] (%) |
| Randomized[b] | | | 10136 |
| Vaccinated | 5081 | 5044 | 10125 (99.9) |
| Safety population | 5081 | 5044 | 10125 (99.9) |
| HIV-positive | 26 | 24 | 50 (0.5) |
| Excluded from safety population | | | 11 (0.1) |
| Reason for exclusion | | | |
| Participant did not receive study intervention | | | 11 (0.1) |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of participants with the specified characteristic or the total sample.
b. This value is the denominator for the percentage calculations.
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(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_s003_pop_all

### 4.4.2. Efficacy Populations

The proportions of participants included in the efficacy populations were similar in the BNT162b2 and placebo groups (Table 7).

The evaluable efficacy population included 9968 participants (98.3%) in both the BNT162b2 and placebo groups. Participants without evidence of SARS-CoV-2 infection prior to 7 days post-booster were balanced for the BNT162b2 and placebo groups: 4708 (92.5%) and 4685 (92.8%), respectively.

In total, 168 participants (1.7%) were excluded from the evaluable efficacy population, because of important PDs on or prior to 7 days after booster vaccination (1.5%), not meeting all eligibility criteria after randomization into the booster study (1.4%), or not receiving vaccine as randomized (0.1%). There was no imbalance across the groups in the exclusions.

A total of 49 (0.5%) participants in the evaluable efficacy population had confirmed stable HIV disease, including 25 in the BNT162b2 group and 24 in the placebo group (Table 7). Of these, participants without evidence of SARS-CoV-2 infection prior to 7 days post-booster were balanced for the BNT162b2 and placebo groups: 19 (0.4%) and 21 (0.4%), respectively. HIV-positive participants were included in this efficacy population summary but not included in the overall efficacy analyses.

For all participants excluded from the evaluable efficacy population because of important PDs on or prior to 7 days after booster vaccination, most deviations in the BNT162b2 and placebo groups (98.8% and 90.8%, respectively) were related to not meeting eligibility criteria (Supplemental Table 14.6).

**Table 7. Efficacy Populations – Blinded Follow-Up Period**

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) n[a] (%) | Placebo n[a] (%) | Total n[a] (%) |
| Randomized[b] | 5088 (100.0) | 5048 (100.0) | 10136 (100.0) |
| All-available efficacy population | 5082 (99.9) | 5043 (99.9) | 10125 (99.9) |
| HIV-positive | 26 (0.5) | 24 (0.5) | 50 (0.5) |
| Participants without evidence of infection prior to 7 days after booster vaccination | 4775 (93.8) | 4753 (94.2) | 9528 (94.0) |
| HIV-positive | 20 (0.4) | 21 (0.4) | 41 (0.4) |
| Participants excluded from the all-available efficacy population | 6 (0.1) | 5 (0.1) | 11 (0.1) |
| Reason for exclusion | | | |
| Did not receive vaccination | 6 (0.1) | 5 (0.1) | 11 (0.1) |
| Evaluable efficacy population | 5002 (98.3) | 4966 (98.4) | 9968 (98.3) |
| HIV-positive | 25 (0.5) | 24 (0.5) | 49 (0.5) |
| Participants without evidence of infection prior to 7 days after booster vaccination | 4708 (92.5) | 4685 (92.8) | 9393 (92.7) |
| HIV-positive | 19 (0.4) | 21 (0.4) | 40 (0.4) |
| Participants excluded from evaluable efficacy population | 86 (1.7) | 82 (1.6) | 168 (1.7) |
| Reason for exclusion[c] | | | |
| Randomized but did not meet all eligibility criteria | 76 (1.5) | 69 (1.4) | 145 (1.4) |
| Did not receive vaccination as randomized | 7 (0.1) | 5 (0.1) | 12 (0.1) |
| Had other important protocol deviations on or prior to 7 days after booster vaccination | 80 (1.6) | 76 (1.5) | 156 (1.5) |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of participants with the specified characteristic.
b. These values are the denominators for the percentage calculations.
c. Participants may have been excluded for more than 1 reason.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 16MAR2022 (01:38)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: /lida2_ubBIA/C4591031_A_SBLA/adsl_eff_pop

## 4.5. Demographic and Other Baseline Characteristics

### 4.5.1. Safety Population

#### 4.5.1.1. Overall

Demographic characteristics for all participants in the safety population were similar in the BNT162b2 and placebo groups (Table 8). Overall, most participants were White (79.0%), followed by 9.2% Black or African American participants, 5.5% Asian participants, and 4.0% multiracial participants. There were 14.9% Hispanic/Latino participants. The median age at the time of study vaccination was 53.0 years, and 49.1% of participants were male. Most study participants (85.9%) were enrolled in the US.

Obese participants made up 35.9% of the safety population.

In total, 551 participants (5.4%) had baseline positive status for evidence of prior infection with SARS-CoV-2, which was balanced across the BNT162b2 and placebo groups.

**Table 8. Demographic Characteristics – Safety Population**

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5081) n[b] (%) | Placebo (N[a]=5044) n[b] (%) | Total (N[a]=10125) n[b] (%) |
| Sex | | | |
| Male | 2457 (48.4) | 2518 (49.9) | 4975 (49.1) |
| Female | 2624 (51.6) | 2526 (50.1) | 5150 (50.9) |
| Race | | | |
| White | 3997 (78.7) | 4003 (79.4) | 8000 (79.0) |
| Black or African American | 471 (9.3) | 460 (9.1) | 931 (9.2) |
| American Indian or Alaska Native | 86 (1.7) | 91 (1.8) | 177 (1.7) |
| Asian | 288 (5.7) | 269 (5.3) | 557 (5.5) |
| Native Hawaiian or other Pacific Islander | 8 (0.2) | 11 (0.2) | 19 (0.2) |
| Multiracial | 208 (4.1) | 196 (3.9) | 404 (4.0) |
| Not reported | 23 (0.5) | 14 (0.3) | 37 (0.4) |
| Ethnicity | | | |
| Hispanic/Latino | 760 (15.0) | 751 (14.9) | 1511 (14.9) |
| Non-Hispanic/non-Latino | 4309 (84.8) | 4285 (85.0) | 8594 (84.9) |
| Not reported | 12 (0.2) | 8 (0.2) | 20 (0.2) |
| Country | | | |
| Brazil | 580 (11.4) | 584 (11.6) | 1164 (11.5) |
| South Africa | 134 (2.6) | 134 (2.7) | 268 (2.6) |
| USA | 4367 (85.9) | 4326 (85.8) | 8693 (85.9) |
| Age group (at vaccination) | | | |
| 16-55 Years | 2823 (55.6) | 2797 (55.5) | 5620 (55.5) |
| >55 Years | 2258 (44.4) | 2247 (44.5) | 4505 (44.5) |

**Table 8. Demographic Characteristics – Safety Population**

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5081) n[b] (%) | Placebo (N[a]=5044) n[b] (%) | Total (N[a]=10125) n[b] (%) |
| 16-17 Years | 46 (0.9) | 44 (0.9) | 90 (0.9) |
| 18-55 Years | 2777 (54.7) | 2753 (54.6) | 5530 (54.6) |
| 56-64 Years | 1083 (21.3) | 1059 (21.0) | 2142 (21.2) |
| 65+ Years | 1175 (23.1) | 1188 (23.6) | 2363 (23.3) |
| Age at vaccination (years) | | | |
| Mean (SD) | 51.8 (15.24) | 51.7 (15.33) | 51.7 (15.28) |
| Median | 53.0 | 53.0 | 53.0 |
| Min, max | (16, 86) | (16, 87) | (16, 87) |
| Baseline SARS-CoV-2 status | | | |
| Positive[c] | 289 (5.7) | 262 (5.2) | 551 (5.4) |
| Negative[d] | 4785 (94.2) | 4775 (94.7) | 9560 (94.4) |
| Unknown | 7 (0.1) | 7 (0.1) | 14 (0.1) |
| Body mass index (BMI) | | | |
| Underweight (<18.5 kg/m$^2$) | 57 (1.1) | 49 (1.0) | 106 (1.0) |
| Normal weight (≥18.5-24.9 kg/m$^2$) | 1431 (28.2) | 1457 (28.9) | 2888 (28.5) |
| Overweight (≥25.0-29.9 kg/m$^2$) | 1769 (34.8) | 1728 (34.3) | 3497 (34.5) |
| Obese (≥30.0 kg/m$^2$) | 1822 (35.9) | 1810 (35.9) | 3632 (35.9) |
| Missing | 2 (0.0) | 0 | 2 (0.0) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 14MAR2022 (08:59)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_s005_demo

Participants in the safety population had a diverse medical history profile that is consistent with that of prior analyses of Phase 2/3 C4591001 participants. Medical history SOCs were balanced across the BNT162b2 and placebo groups. In the BNT162b2 recipients, conditions in the surgical and medical procedures (48.3%), metabolism and nutrition disorders (35.9%), and immune system disorders (35.7%, including seasonal allergy in 20.3%) SOCs were most frequently reported.

Baseline Charlson comorbidities were reported in 2397 participants (23.7%) in the safety population and were balanced across the BNT162b2 and placebo groups. The most common

comorbidities reported overall were chronic pulmonary disease (9.2%), diabetes without chronic complication (8.4%), and any malignancy (4.7%).

The younger age group (16 to 55 years of age) made up 55.5% of the safety population; this included 90 participants (0.9%) who were 16 to 17 years of age. The older age group (>55 years of age) made up 44.5% of the safety population; this included 2363 participants (23.3%) who were ≥65 years of age. Demographics (except for age) in the younger and older age groups were similar to the overall safety population. The median age in the younger group was 42.0 years, and the median age in the older group was 65.0 years.

Baseline Charlson comorbidities were reported at higher frequencies in the older group (33.3%) than in the younger group (16.0%). The most commonly reported comorbidities in both age groups were the same as reported in the safety population overall, albeit reported at higher frequencies in the older group compared to the younger group.

**Participants Not Known to be HIV-Positive**

Demographic characteristics for participants randomized that were not known to be HIV positive were similar to those of the overall safety population (Table 8).

**HIV-Positive Participants**

Demographic characteristics for HIV-positive participants in the safety population (N=26 in the BNT162b2 group and N=24 in the placebo group) were similar to the overall safety population, with several exceptions. The proportion of White HIV-positive participants was 42.0% with 54.0% Black or African American, and other race groups reported at 2.0% each. There were 10.0% Hispanic/Latino HIV-positive participants. The median age at the time of study vaccination was 51.0 years, and 64.0% of HIV-positive participants were male. Most HIV-positive participants were enrolled in the US (62.0%) and South Africa (34.0%). Obese HIV-positive participants made up 48.0% of the safety population. In total, 9 HIV-positive participants (18.0%) had baseline positive status for evidence of prior infection with SARS-CoV-2.

Most HIV-positive participants (60.0%) had a CD4+ T cell count >500 cells/mm$^3$ and most (70.0%) had <50 copies/mL of HIV RNA.

Additional data are presented in the following:

| | |
|---|---|
| Demographic Characteristics, by Age Group – Safety Population | Supplemental Tables 14.7-8 |
| Demographic Characteristics – Participants Not Known To Be HIV-Positive – Safety Population | Supplemental Table 14.9 |
| Demographic Characteristics – HIV-Positive Participants – Safety Population | Supplemental Table 14.10 |
| Medical History – Safety Population | Supplemental Table 14.11 |
| Baseline Charlson Comorbidities – Safety Population | Supplemental Table 14.12 |
| Baseline Charlson Comorbidities, by Age Group – Safety Population | Supplemental Tables 14.13-14.14 |

#### 4.5.1.2. Participants With At Least 6 Months of Follow-Up Time – Original BNT162b2 Participants

Demographic characteristics for all original BNT162b2 recipients who had at least 6 months of follow-up time after booster vaccination (N=5025) are presented in Supplemental Table 14.15 and were similar to those in the BNT162b2 group overall (N=5081; Table 8).

#### 4.5.1.3. Original Placebo Participants Who Then Received BNT162b2

Demographic characteristics for all original placebo recipients who then received BNT162b2 later during the open-label follow-up period (N=4419) are presented in Supplemental Table 14.16 and were similar to those in the placebo group overall (N=5044; Table 8).

### 4.5.2. Efficacy Populations

Demographics of participants in the evaluable efficacy population without evidence of infection prior to 7 days after booster vaccination were similar in the BNT162b2 and placebo groups (Table 9). This analysis population had similar demographics compared to the overall safety population (refer to Section 4.5.1.1).

Most participants were White (80.1%), followed by 8.0% Black or African American participants, 5.7% Asian participants, and 3.9% multiracial participants. There were 14.7% Hispanic/Latino participants. The median age at the time of study vaccination was 53.0 years, and 49.5% of participants were male. Most study participants (87.0%) were enrolled in the US.

The younger age group (16 to 55 years of age) made up 54.8% of the population; this included 78 participants (0.8%) who were 16 to 17 years of age. The older age group (>55 years of age) made up 45.2% of the population; this included 2237 participants (23.8%) who were ≥65 years of age.

Obese participants made up 35.4% of the population. Baseline comorbidities (including Charlson comorbidities and obesity, which increase an individual's risk of developing severe COVID-19) were reported in 48.4% of the population and were balanced across the BNT162b2 and placebo groups.

Demographic characteristics for participants with or without evidence of infection prior to 7 days after booster vaccination (evaluable efficacy population) and the all-available efficacy population were also similar to those in the safety population.

#### Participants Not Known to be HIV-Positive

Demographic characteristics for participants without evidence of infection prior to 7 days after booster vaccination (evaluable efficacy population) who were not known to be HIV-positive were similar to those in the overall evaluable efficacy and overall safety populations.

**Table 9. Demographic Characteristics – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population**

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4708) n[b] (%) | Placebo (N[a]=4685) n[b] (%) | Total (N[a]=9393) n[b] (%) |
| Sex | | | |
| Male | 2294 (48.7) | 2353 (50.2) | 4647 (49.5) |
| Female | 2414 (51.3) | 2332 (49.8) | 4746 (50.5) |
| Race | | | |
| White | 3763 (79.9) | 3761 (80.3) | 7524 (80.1) |
| Black or African American | 371 (7.9) | 376 (8.0) | 747 (8.0) |
| American Indian or Alaska Native | 82 (1.7) | 88 (1.9) | 170 (1.8) |
| Asian | 274 (5.8) | 259 (5.5) | 533 (5.7) |
| Native Hawaiian or other Pacific Islander | 7 (0.1) | 11 (0.2) | 18 (0.2) |
| Multiracial | 189 (4.0) | 176 (3.8) | 365 (3.9) |
| Not reported | 22 (0.5) | 14 (0.3) | 36 (0.4) |
| Ethnicity | | | |
| Hispanic/Latino | 689 (14.6) | 688 (14.7) | 1377 (14.7) |
| Non-Hispanic/non-Latino | 4009 (85.2) | 3989 (85.1) | 7998 (85.1) |
| Not reported | 10 (0.2) | 8 (0.2) | 18 (0.2) |
| Country | | | |
| Brazil | 519 (11.0) | 527 (11.2) | 1046 (11.1) |
| South Africa | 79 (1.7) | 97 (2.1) | 176 (1.9) |
| USA | 4110 (87.3) | 4061 (86.7) | 8171 (87.0) |
| Age group (years) | | | |
| 16-55 | 2582 (54.8) | 2570 (54.9) | 5152 (54.8) |
| >55 | 2126 (45.2) | 2115 (45.1) | 4241 (45.2) |
| ≥65 | 1120 (23.8) | 1117 (23.8) | 2237 (23.8) |
| 16-17 | 41 (0.9) | 37 (0.8) | 78 (0.8) |
| 16-25 | 223 (4.7) | 249 (5.3) | 472 (5.0) |
| 16-30 | 460 (9.8) | 473 (10.1) | 933 (9.9) |
| 18-30 | 419 (8.9) | 436 (9.3) | 855 (9.1) |
| 31-40 | 722 (15.3) | 692 (14.8) | 1414 (15.1) |
| 16-40 | 1182 (25.1) | 1165 (24.9) | 2347 (25.0) |
| 41-50 | 888 (18.9) | 920 (19.6) | 1808 (19.2) |
| 51-60 | 1045 (22.2) | 1011 (21.6) | 2056 (21.9) |
| >60 | 1593 (33.8) | 1589 (33.9) | 3182 (33.9) |
| 16-64 | 3588 (76.2) | 3568 (76.2) | 7156 (76.2) |
| 18-64 | 3547 (75.3) | 3531 (75.4) | 7078 (75.4) |
| 55-64 | 1125 (23.9) | 1084 (23.1) | 2209 (23.5) |
| 65-74 | 869 (18.5) | 871 (18.6) | 1740 (18.5) |
| ≥75 | 251 (5.3) | 246 (5.3) | 497 (5.3) |

**Table 9. Demographic Characteristics – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population**

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4708) n[b] (%) | Placebo (N[a]=4685) n[b] (%) | Total (N[a]=9393) n[b] (%) |
| 75-85 | 250 (5.3) | 243 (5.2) | 493 (5.2) |
| >85 | 1 (0.0) | 3 (0.1) | 4 (0.0) |
| Age at vaccination (years) | | | |
| Mean (SD) | 52.0 (15.21) | 52.0 (15.25) | 52.0 (15.23) |
| Median | 53.0 | 53.0 | 53.0 |
| Min, max | (16, 86) | (16, 87) | (16, 87) |
| Comorbidities[c] | | | |
| Yes | 2268 (48.2) | 2280 (48.7) | 4548 (48.4) |
| No | 2440 (51.8) | 2405 (51.3) | 4845 (51.6) |
| Body mass index (BMI) | | | |
| Underweight (<18.5 kg/m$^2$) | 53 (1.1) | 45 (1.0) | 98 (1.0) |
| Normal weight (≥18.5-24.9 kg/m$^2$) | 1337 (28.4) | 1364 (29.1) | 2701 (28.8) |
| Overweight (≥25.0-29.9 kg/m$^2$) | 1659 (35.2) | 1610 (34.4) | 3269 (34.8) |
| Obese (≥30.0 kg/m$^2$) | 1657 (35.2) | 1666 (35.6) | 3323 (35.4) |
| Missing | 2 (0.0) | 0 | 2 (0.0) |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least 1 Charlson Comorbidity Index category or a BMI ≥30 kg/m$^2$.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 16MAR2022 (08:50)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_demo_7d_eval_eff_new

Additional data are presented in the following:

| | |
|---|---|
| Demographic Characteristics – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population | Supplemental Table 14.17 |
| Demographic Characteristics – Blinded Follow-Up Period – All-Available Efficacy Population | Supplemental Table 14.18 |
| Demographic Characteristics (Participants Not Known To Be HIV-Positive) – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population | Supplemental Table 14.19 |

### 4.6. Prior, Concomitant, and Post-Intervention Therapy

Concomitant vaccines received after the booster dose during the study were reported by 8.9% and 17.7% of participants in the BNT162b2 and placebo groups, respectively (Supplemental Table 14.20).

In the BNT162b2 group, the most common vaccine received after booster vaccination was influenza vaccine (7.5%).

In the placebo group, the most common vaccines received after booster vaccination were influenza vaccine (11.8%), BNT162b2 (reported by World Health Organization name, TOZINAMERAN) (4.6%), and COVID-19 mRNA vaccine (reported as MRNA 1273) (0.5%). The COVID-19 vaccines were received outside of the C4591031 study. Note that data after unblinding (per protocol) or receiving the COVID-19 vaccine outside of the study were excluded from the blinded follow-up period summary.

### 4.7. Follow-up Time

#### 4.7.1. Safety Population

##### 4.7.1.1. Overall

In the safety population, the median duration of blinded follow-up after receipt of the booster vaccination for the safety population was 2.8 months as of the data cutoff date (Table 10). In participants originally randomized to the BNT162b2 group, the total exposure from booster vaccination to the data cutoff date was ≥6 months for most participants (98.9%).

Follow-up times after booster vaccination in the younger (16 to 55 years) and older (>55 years) age groups (Supplemental Tables 14.21 and 14.22) were similar to those in Table 10.

**Table 10. Follow-Up Time After Booster Vaccination – Safety Population**

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5081) n[b] (%) | Placebo (N[a]=5044) n[b] (%) | Total (N[a]=10125) n[b] (%) |
| Participants (%) with length of follow-up of: | | | |
| Blinded follow-up period | | | |
| <2 Months | 153 (3.0) | 263 (5.2) | 416 (4.1) |
| ≥2 Months to <4 months | 4033 (79.4) | 4395 (87.1) | 8428 (83.2) |
| ≥4 Months to <6 months | 330 (6.5) | 326 (6.5) | 656 (6.5) |
| ≥6 Months | 565 (11.1) | 60 (1.2) | 625 (6.2) |
| Mean (SD) | 3.4 (1.45) | 2.9 (0.82) | 3.2 (1.20) |
| Median | 2.9 | 2.8 | 2.8 |
| Min, max | (0.4, 7.5) | (0.3, 7.5) | (0.3, 7.5) |

**Table 10. Follow-Up Time After Booster Vaccination – Safety Population**

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5081) n[b] (%) | Placebo (N[a]=5044) n[b] (%) | Total (N[a]=10125) n[b] (%) |
| Total exposure from booster vaccination to the cutoff date | | | |
| <2 Months | 9 (0.2) | | |
| ≥2 Months to <4 months | 25 (0.5) | | |
| ≥4 Months to <6 months | 22 (0.4) | | |
| ≥6 Months | 5025 (98.9) | | |
| Mean (SD) | 7.0 (0.49) | | |
| Median | 7.1 | | |
| Min, max | (1.0, 8.0) | | |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
Note: Follow-up time for blinded period was calculated from booster vaccination to the cutoff date or withdrawal date or the day before date of unblinding (per protocol) or the day before date of receiving COVID-19 vaccine off study, whichever date was earlier.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 20MAR2022 (23:20)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_fu_d2_saf

#### 4.7.1.2. Original Placebo Participants Who Then Received BNT162b2

For all original placebo recipients who then received BNT162b2 later during the open-label follow-up period, the median duration of follow-up was 3.9 months, with most participants having ≥3 months to <4 months (42.5%) or ≥4 months (45.3%) of follow up (Supplemental Table 14.23).

### 4.7.2. Efficacy Populations

For participants without evidence of infection prior to 7 days after booster vaccination in the evaluable efficacy population, the median duration of blinded follow-up after booster vaccination was 2.8 months as of the data cutoff date (Table 11) and was similar to the safety population (Table 10). Of these participants originally randomized to the BNT162b2 group, the total exposure from booster vaccination to the data cutoff date was ≥6 months for most participants (99.0%).

Follow-up times after booster vaccination for participants with or without evidence of infection prior to 7 days after booster vaccination in the evaluable efficacy population (Supplemental Table 14.24) were similar to those in Table 11.

## Table 11. Follow-Up Time After Booster Vaccination – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4708) n[b] (%) | Placebo (N[a]=4685) n[b] (%) | Total (N[a]=9393) n[b] (%) |
| Participants (%) with length of follow-up of: | | | |
| Blinded follow-up period | | | |
| <2 Months | 139 (3.0) | 243 (5.2) | 382 (4.1) |
| ≥2 Months to <4 months | 3782 (80.3) | 4091 (87.3) | 7873 (83.8) |
| ≥4 Months to <6 months | 299 (6.4) | 298 (6.4) | 597 (6.4) |
| ≥6 Months | 488 (10.4) | 53 (1.1) | 541 (5.8) |
| Mean (SD) | 3.3 (1.42) | 2.9 (0.81) | 3.1 (1.17) |
| Median | 2.9 | 2.8 | 2.8 |
| Min, max | (0.4, 7.5) | (0.3, 7.5) | (0.3, 7.5) |
| Total exposure from booster vaccination to the cutoff date | | | |
| <2 Months | 7 (0.1) | | |
| ≥2 Months to <4 months | 22 (0.5) | | |
| ≥4 Months to <6 months | 19 (0.4) | | |
| ≥6 Months | 4660 (99.0) | | |
| Mean (SD) | 7.0 (0.47) | | |
| Median | 7.1 | | |
| Min, max | (1.0, 8.0) | | |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants who had no serological or virological evidence (prior to 7 days after receipt of the booster vaccination) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visit 1, and had a negative NAAT [nasal swab] at any unscheduled visit prior to 7 days after booster vaccination) were included in the analysis.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
Note: Follow-up time for blinded period was calculated from booster vaccination to the cutoff date or withdrawal date or the day before date of unblinding (per protocol) or the day before date of receiving COVID-19 vaccine off study, whichever date was earlier.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 20MAR2022 (23:20)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_fu_d2_wo_eval

# 5. EVALUATION OF RESPONSE TO STUDY INTERVENTION

## 5.1. Efficacy

In this CSR, updated efficacy analyses of a single booster dose of BNT162b2 30 µg were performed with all cases accrued during blinded placebo-controlled follow-up (through the cutoff date of 08 February 2022), including subgroup analyses, and for FDA-defined severe cases and CDC-defined severe cases (Section 5.1.1). Also presented is an analysis of COVID-19 cases through the entire study follow-up period in participants who received BNT162b2 initially or subsequently after unblinding (Section 5.1.2).

### 5.1.1. Updated Efficacy Results – Blinded Placebo-Controlled Follow-Up Period

For this updated efficacy analysis, participant eligibility to be unblinded from 24 September 2021 (Section 3.1.1). As shown in the following sections, this resulted in a substantial reduction over time of blinded participants.

#### 5.1.1.1. Updated Analysis of Primary Efficacy Endpoints – COVID-19 Cases

##### 5.1.1.1.1. Vaccine Efficacy Without Evidence of SARS-CoV-2 Infection Prior to 7 Days After Booster Dose

In the evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days after booster vaccination, the observed RVEs of 95.6% and 95.1% for cases confirmed from ≥7 days to <2 months and from ≥2 to <4 months after booster vaccination, respectively (Table 12), were consistent with the 95.3% reported in the 2-month analysis interim CSR (dated 18 November 2021). Relatively few participants remained in the placebo group for time points ≥4 months after booster vaccination (>90% reduction [to 318 participants] at ≥4 to <5 months and >99% reduction [to 43 participants] at ≥6 months) and there were very few cases (≤2) in placebo participants, precluding a precise estimation of RVE. This resulted in an overall RVE, confirmed from at least 7 days after the booster vaccination, of 63.9% (2-sided 95% CI: 51.1%, 73.5%), based on 63 and 148 cases in the BNT162b2 and placebo groups, respectively. Of note 53 of the 63 cases in the BNT162b2 group occurred ≥5 months after booster vaccination; this was the time when the Omicron variant became the predominant strain and fewer placebo participants remained blinded to provide appropriate control for the RVE estimate for that period. The estimate of the overall RVE, therefore, should be interpreted with caution. Further discussion of COVID-19 incidence by time after booster vaccination and by date (relative to whether the Delta or Omicron variant was predominant) is provided in Section 5.3.1.

**Table 12. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population**

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4689) | | Placebo (N[a]=4664) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First COVID-19 occurrence from 7 days after booster vaccination | 63 | 1.098 (4639) | 148 | 0.932 (4601) | 63.9 | (51.1, 73.5) |
| ≥7 Days after booster vaccination to <2 months after booster vaccination | 5 | 0.620 (4639) | 110 | 0.600 (4601) | 95.6 | (89.4, 98.6) |
| ≥2 Months after booster vaccination to <4 months after booster vaccination | 2 | 0.363 (4497) | 35 | 0.313 (4250) | 95.1 | (80.9, 99.4) |
| ≥4 Months after booster vaccination to <5 months after booster vaccination | 3 | 0.045 (764) | 0 | 0.012 (318) | UND | (NA, NA) |
| ≥5 Months after booster vaccination to <6 months after booster vaccination | 30 | 0.035 (502) | 2 | 0.004 (69) | -70.9 | (-1375.4, 56.6) |
| ≥6 Months after booster vaccination | 23 | 0.035 (435) | 1 | 0.003 (43) | -90.8 | (-7757.8, 69.0) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein-binding; NA = not applicable; NAAT = nucleic acid amplification test; RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster); SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; UND = undefined.
Note: Participants who had no serological or virological evidence (prior to 7 days after receipt of the booster vaccination) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visit 1, and had a negative NAAT [nasal swab] at any unscheduled visit prior to 7 days after booster vaccination) were included in the analysis.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period for the overall row and from the start to the end of the range stated for each time interval.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 22MAR2022 (10:28)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_ve_cov_7d_wo_eval

### 5.1.1.1.2. Vaccine Efficacy With or Without Evidence of SARS-CoV-2 Infection Prior to 7 Days After Booster Dose

In the evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days after booster vaccination, the observed RVEs of 94.8% and 95.1% for cases confirmed from ≥7 days to <2 months and from ≥2 to <4 months after booster vaccination, respectively (Table 13), were consistent with the 94.6% reported in the 2-month analysis interim CSR (dated 18 November 2021). Relatively few participants remained in the placebo group for time points ≥4 months after booster vaccination (>90% reduction [to 345 participants] at ≥4 to <5 months and >99% reduction [to 47 participants] at ≥6 months) and there were very few cases (≤2) in placebo participants, precluding a precise estimation of

RVE. This resulted in an overall RVE, confirmed from at least 7 days after the booster vaccination, of 62.4% (2-sided 95% CI: 49.5%, 72.2%), based on 67 and 150 cases in the BNT162b2 and placebo groups, respectively. The overall RVE should be interpreted with caution, for reasons described in Section 5.1.1.1.1. Further discussion of COVID-19 incidence by time after booster vaccination and by date (relative to whether the Delta or Omicron variant was predominant) is provided in Section 5.3.1.

**Table 13. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population**

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4977) | | Placebo (N[a]=4942) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First COVID-19 occurrence from 7 days after booster vaccination | 67 | 1.173 (4903) | 150 | 0.989 (4846) | 62.4 | (49.5, 72.2) |
| ≥7 Days after booster vaccination to <2 months after booster vaccination | 6 | 0.655 (4903) | 111 | 0.633 (4846) | 94.8 | (88.3, 98.1) |
| ≥2 Months after booster vaccination to <4 months after booster vaccination | 3 | 0.390 (4754) | 35 | 0.335 (4489) | 95.1 | (80.9, 99.4) |
| ≥4 Months after booster vaccination to <5 months after booster vaccination | 4 | 0.049 (846) | 0 | 0.013 (345) | UND | (NA, NA) |
| ≥5 Months after booster vaccination to <6 months after booster vaccination | 31 | 0.039 (559) | 2 | 0.004 (75) | -72.8 | (-1390.5, 56.0) |
| ≥6 Months after booster vaccination | 24 | 0.039 (490) | 2 | 0.003 (47) | 3.9 | (-739.2, 76.1) |

Abbreviations: NA = not applicable; RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster); UND = undefined.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period for the overall row and from the start to the end of the range stated for each time interval.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 22MAR2022 (10:31)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_ve_cov_7d_eval

### 5.1.1.1.3. All Confirmed Cases of COVID-19 – All-Available Efficacy Population

A number of confirmed cases of COVID-19 are not captured in the analyses of the primary endpoints for the evaluable efficacy population because they either occurred in participants who were excluded from the evaluable efficacy population, or occurred less than 7 days after booster vaccination.

All reports of COVID-19 in the all-available efficacy (mITT) population, with onset at any time after booster vaccination, are presented in Table 14. In the all-available efficacy population, the observed RVEs of 94.9% and 95.1% for cases confirmed from ≥7 days to <2 months and from ≥2 to <4 months after booster vaccination, respectively, were consistent with those reported in the 2-month analysis interim CSR (dated 18 November 2021; 94.8% and 93.3%, respectively). Relatively few participants remained in the placebo group for time points ≥4 months after booster vaccination (>90% reduction [to 351 participants] at ≥4 to <5 months and >99% reduction [to 48 participants] at ≥6 months) and there were very few cases (≤2) in placebo participants, precluding a precise estimation of RVE. This resulted in an overall RVE, confirmed from at least 7 days after the booster vaccination, of 61.2% (2-sided 95% CI: 48.8%, 70.8%), based on 76 and 167 cases in the BNT162b2 and placebo groups, respectively. The overall RVE should be interpreted with caution, for reasons described in Section 5.1.1.1.1.

The Kaplan-Meier curves show the case accrual from booster vaccination onwards during the blinded follow-up period, with the 3 severe cases denoted in with 'S' on the placebo curve (no severe cases were reported in the BNT162b2 group) (Figure 1). The curve of COVID-19 cases in the BNT162b2 group remains relatively flat and begins to increase at ~140 days after booster vaccination, with the majority of these cases occurring from late December 2021 to the data cutoff date of 08 February 2022 (Appendix 16.2.8.1) when the highly transmissible Omicron variant became predominant.[14] Severe COVID-19 cases reported are discussed further in Section 5.1.1.2. As noted earlier, the number of at-risk participants in the placebo group decreased much faster in that time period compared to the BNT162b2 group.

Further discussion of COVID-19 incidence by time after booster vaccination and by date (relative to whether the Delta or Omicron variant was predominant) is provided in Section 5.3.1.

**Table 14. Vaccine Efficacy – First COVID-19 Occurrence After Booster Vaccination – Blinded Follow-Up Period – All-Available Efficacy Population**

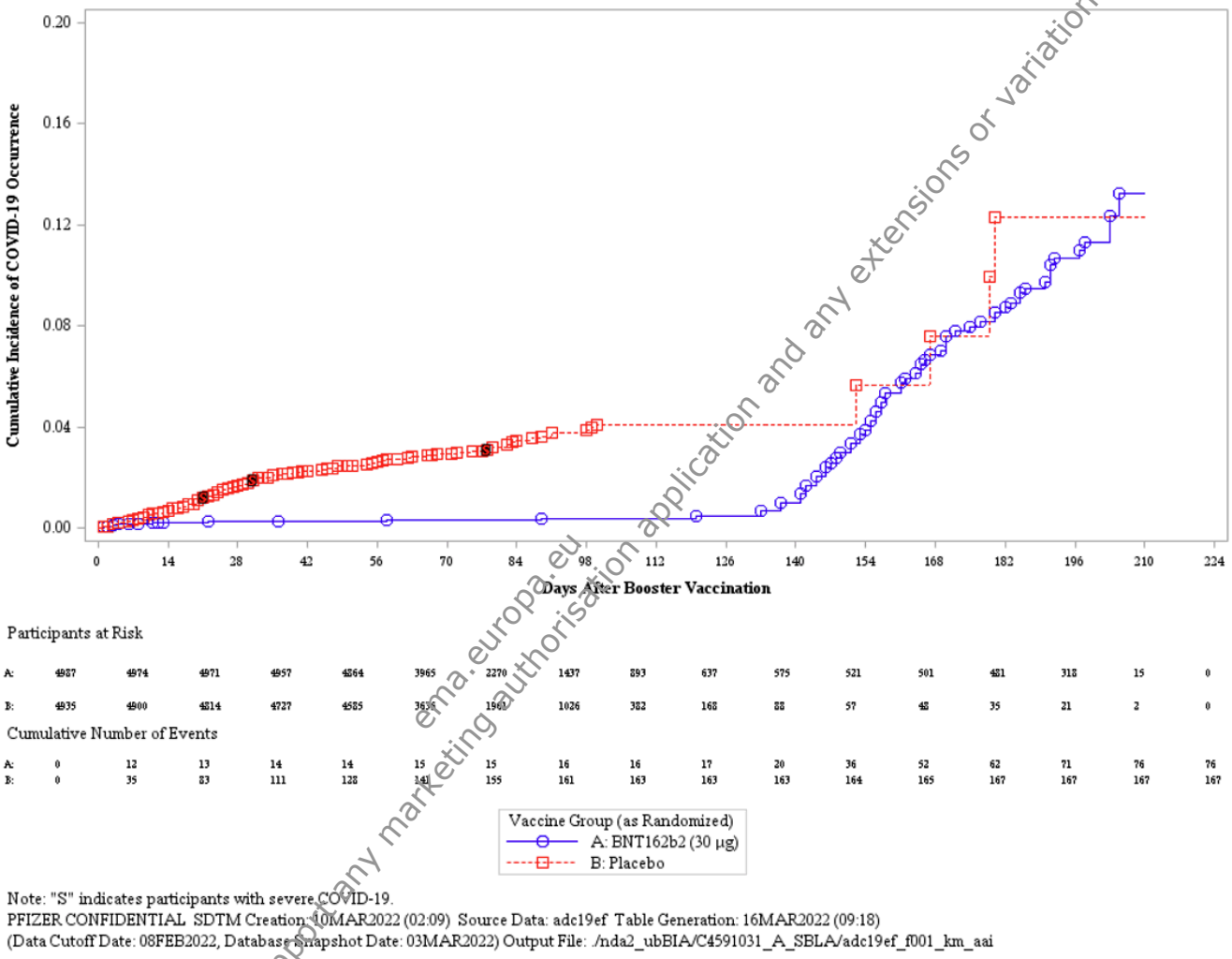
| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5056) | | Placebo (N[a]=5019) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First COVID-19 occurrence after booster vaccination | 76 | 1.288 (4987) | 167 | 1.098 (4935) | 61.2 | (48.8, 70.8) |
| Booster vaccination to 7 days after booster vaccination | 8 | 0.095 (4987) | 15 | 0.094 (4935) | 47.2 | (-32.5, 80.6) |
| ≥7 Days after booster vaccination to <2 months after booster vaccination | 6 | 0.665 (4979) | 113 | 0.642 (4920) | 94.9 | (88.5, 98.2) |
| ≥2 Months after booster vaccination to <4 months after booster vaccination | 2 | 0.396 (4825) | 35 | 0.340 (4550) | 95.1 | (80.9, 99.4) |

## Table 14. Vaccine Efficacy – First COVID-19 Occurrence After Booster Vaccination – Blinded Follow-Up Period – All-Available Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5056) | | Placebo (N[a]=5019) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| ≥4 Months after booster vaccination to <5 months after booster vaccination | 4 | 0.050 (861) | 0 | 0.014 (351) | UND | (NA, NA) |
| ≥5 Months after booster vaccination to <6 months after booster vaccination | 32 | 0.040 (571) | 2 | 0.005 (79) | -81.0 | (-1458.6, 53.8) |
| ≥6 Months after booster vaccination | 24 | 0.040 (501) | 2 | 0.003 (48) | 5.9 | (-721.1, 76.6) |

Abbreviations: NA = not applicable; RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster); UND = undefined.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from the booster vaccination to the end of the surveillance period for the overall row and from the start to the end of the range stated for each time interval.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 22MAR2022 (10:31)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_ve_cov_aai

**Figure 1. Cumulative Incidence Curves for the First COVID-19 Occurrence After Booster Vaccination – Blinded Follow-Up Period – All-Available Efficacy Population**




Note: "S" indicates participants with severe COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adc19ef Table Generation: 16MAR2022 (09:18)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_f001_km_aai

Additional data are presented in the following:

| | |
|---|---|
| Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – All-Available Efficacy Population | Supplemental Table 14.25 |
| Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – All-Available Efficacy Population | Supplemental Table 14.26 |
| Listing of Participants With First COVID-19 Occurrence After Booster Vaccination – Blinded Follow-Up Period – All-Available Efficacy Population | Listing 16.2.8.1 |

### 5.1.1.1.4. Signs and Symptoms of COVID-19

Based on cases up to the data cutoff date, signs and symptoms associated with cases confirmed ≥7 days post-booster in the evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days post-booster were associated with 63 cases in the BNT162b2 group and 148 cases in the placebo group (Table 15). The frequencies of participants with ≥4 reported signs and symptoms were generally higher in the placebo group (range: 10.1-10.8%) than the BNT162b2 group (range: 3.2-9.5%). Across vaccine groups, the most commonly reported were new or increased cough (71.1%) and sore throat (45.0%, including 60.3% in the BNT162b2 group vs 38.5% in the placebo group). Other signs and symptoms were reported in the BNT162b2 group at similar or lower frequencies than the placebo group.

The overall profiles and patterns of signs and symptoms associated with cases were similar in the evaluable efficacy population with or without evidence of SARS-CoV-2 infection prior to 7 days post-booster, as well as the all-available efficacy population.

**Table 15. Signs and Symptoms of First COVID-19 Occurrence From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population**

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| Signs and Symptoms | BNT162b2 (30 µg) ($N^a$=63) $n^b$(%) | Placebo ($N^a$=148) $n^b$(%) | Total ($N^a$=211) $n^b$(%) |
| Participants with specific signs and symptoms of COVID-19 | | | |
| Fever | 16 (25.4) | 67 (45.3) | 83 (39.3) |
| New or increased cough | 45 (71.4) | 105 (70.9) | 150 (71.1) |
| New or increased shortness of breath | 2 (3.2) | 19 (12.8) | 21 (10.0) |
| Chills | 27 (42.9) | 56 (37.8) | 83 (39.3) |
| New or increased muscle pain | 16 (25.4) | 68 (45.9) | 84 (39.8) |
| New loss of taste or smell | 5 (7.9) | 47 (31.8) | 52 (24.6) |
| Sore throat | 38 (60.3) | 57 (38.5) | 95 (45.0) |
| Diarrhea | 12 (19.0) | 26 (17.6) | 38 (18.0) |
| Vomiting | 4 (6.3) | 3 (2.0) | 7 (3.3) |
| Participants with specific number of signs and symptoms | | | |
| 1 | 13 (20.6) | 35 (23.6) | 48 (22.7) |
| 2 | 21 (33.3) | 29 (19.6) | 50 (23.7) |
| 3 | 18 (28.6) | 37 (25.0) | 55 (26.1) |
| 4 | 2 (3.2) | 16 (10.8) | 18 (8.5) |
| 5 | 6 (9.5) | 15 (10.1) | 21 (10.0) |
| >5 | 3 (4.8) | 16 (10.8) | 19 (9.0) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants who had no serological or virological evidence (prior to 7 days after receipt of the booster vaccination) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visit 1, and had a negative NAAT [nasal swab] at any unscheduled visit prior to 7 days after the booster vaccination) were included in the analysis.
a. N = number of participants with a first COVID-19 occurrence from 7 days after the booster vaccination in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified criteria meeting the COVID-19 case definition. A participant can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:12) Source Data: adc19ef Table Generation: 16MAR2022 (01:41)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsympt_symp_cov_7d_wo_eval

Additional data are presented in the following:

| | |
|---|---|
| Signs and Symptoms of First COVID-19 Occurrence From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population | Supplemental Table 14.27 |

Signs and Symptoms of First COVID-19 Occurrence After Booster Vaccination – Blinded Follow-Up Period – All-Available Efficacy Population

Supplemental Table 14.28

### 5.1.1.1.5. Vaccine Efficacy by Subgroup

For the evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days post-booster, subgroup analyses were conducted to estimate the overall RVE (from 7 days after booster vaccination). Analyses were based on demographics and baseline characteristics of geography and time to booster vaccination (Table 16), as well as risk factors (Table 17) including specific high-risk specific comorbidities (Table 18). Overall, for most subgroups with enough cases and participants for precise RVE analyses, the confirmed COVID-19 cases from 7 days after booster vaccination were similar to the overall RVE of 63.9% (Table 12).

The subgroup analysis results for estimated RVE were similar for the evaluable efficacy population with or without evidence of SARS-CoV-2 infection prior to 7 days post-booster, as well as the all-available efficacy population.

For participants who were baseline SARS-CoV-2 positive, there were only 8 in the BNT162b2 group and 7 in the placebo group with confirmed COVID-19 cases as of the data cutoff date, precluding meaningful interpretation by baseline status.

**Age, Sex, Race, Ethnicity, Country, and Time to Booster Dose**

For the evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days post-booster, subgroup analyses by demographic and baseline characteristics are shown in Table 16.

*Age*

The observed RVEs for participants in the younger (16 to 55 years) and older (>55 years) age groups were 67.8% (2-sided 95% CI: 52.3%, 78.7%) and 56.6% (2-sided 95% CI: 29.6%, 73.8%), respectively, similar to the overall RVE of 63.9%. Several ages in the analysis included small numbers of cases and participants, which contributed to wide confidence intervals around the point estimate (eg, 16 to 17 years, ≥75 years, and 75 to 85 years of age).

*Sex*

The observed RVE was 72.3% (2-sided 95% CI: 56.5%, 82.9%) for male participants compared to 53.6% (2-sided 95% CI: 29.5%, 69.9%) for female participants.

*Race*

For the White and Black or African American race subgroups (which comprised the majority of the population [Table 9]), the observed RVEs were 59.8% (2-sided 95% CI: 44.4%, 71.2%) and 100.0% (2-sided 95% CI: 74.8%, 100.0%), respectively. The other race

subgroups included a limited numbers of cases and participants, which contributed to wide confidence intervals around the point estimates.

*Ethnicity*

The observed RVE was 40.4% (2-sided 95% CI: -14.9%, 69.8%) for Hispanic/Latino participants and 68.4% (2-sided 95% CI: 55.4%, 78.0%) for non-Hispanic/non-Latino participants.

*Country*

For the US and Brazil (which comprised the majority of the population [Table 9]), the observed RVEs were 63.0% (2-sided 95% CI: 49.6%, 73.1%) and 100.0% (2-sided 95% CI: 56.0%, 100.0%), respectively. South Africa included small numbers of cases and participants, which contributed to wide confidence intervals around the point estimates.

*Time to Booster*

For the subgroup with ≥10 to <12 months between receipt of Dose 2 to receipt of the booster dose (which was the timing for the majority of participants [Table 5]), the observed RVE of 66.3% (2-sided 95% CI: 50.9%, 77.3%) was similar to the overall RVE of 63.9%. Some of the other subgroups included a limited numbers of cases, which contributed to wide confidence intervals around the point estimates.

**Risk Status, Comorbidity**

For the evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days post-booster, subgroup analyses by risk status are shown in Table 17 and by specific high-risk comorbidities in Table 18.

*Risk Status*

Most risk status groups analyzed including those at-risk, obese, and with combinations of high-risk age and risk status showed similar observed RVEs to the overall RVE of 63.9%. A few risk groups in the analysis included small numbers of cases and participants, which contributed to wide confidence intervals around the point estimate (eg, ≥65 years of age and at risk, ≥65 years of age and obese).

*Comorbidity*

Most specific high-risk comorbidities analyzed showed similar observed RVEs to the overall RVE of 63.9%. A few comorbidity groups in the analysis included small numbers of cases and participants, which contributed to wide confidence intervals around the point estimate (eg, any malignancy, cardiovascular).

**Table 16. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination, by Subgroup – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population**

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4689) | | Placebo (N[a]=4664) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First COVID-19 occurrence from 7 days after booster vaccination | | | | | | |
| Overall | 63 | 1.098 (4639) | 148 | 0.932 (4661) | 63.9 | (51.1, 73.5) |
| Age group (years) | | | | | | |
| 16-55 | 36 | 0.604 (2533) | 96 | 0.520 (2518) | 67.8 | (52.3, 78.7) |
| >55 | 27 | 0.494 (2106) | 52 | 0.413 (2083) | 56.6 | (29.6, 73.8) |
| ≥65 | 8 | 0.251 (1112) | 17 | 0.213 (1104) | 60.0 | (2.2, 85.1) |
| 16-17 | 0 | 0.009 (41) | 2 | 0.007 (37) | 100.0 | (-318.5, 100.0) |
| 16-25 | 3 | 0.055 (222) | 8 | 0.053 (245) | 63.3 | (-52.9, 93.7) |
| 16-30 | 8 | 0.113 (455) | 14 | 0.100 (464) | 49.4 | (-29.1, 81.6) |
| 18-30 | 8 | 0.104 (414) | 12 | 0.093 (427) | 40.5 | (-58.4, 78.9) |
| 31-40 | 7 | 0.168 (707) | 34 | 0.142 (681) | 82.7 | (60.3, 93.5) |
| 16-40 | 15 | 0.282 (1162) | 48 | 0.242 (1145) | 73.1 | (51.2, 86.0) |
| 41-50 | 15 | 0.203 (869) | 26 | 0.183 (901) | 48.0 | (-1.9, 74.4) |
| 51-60 | 19 | 0.251 (1028) | 44 | 0.199 (987) | 65.7 | (40.0, 81.1) |
| >60 | 14 | 0.363 (1580) | 30 | 0.308 (1568) | 60.4 | (22.9, 80.6) |
| 16-64 | 55 | 0.847 (3527) | 131 | 0.719 (3497) | 64.4 | (50.8, 74.5) |
| 18-64 | 55 | 0.838 (3486) | 129 | 0.712 (3460) | 63.8 | (50.0, 74.1) |
| 55-64 | 23 | 0.270 (1111) | 38 | 0.216 (1062) | 51.7 | (16.9, 72.5) |
| 65-74 | 7 | 0.194 (862) | 15 | 0.166 (861) | 60.2 | (-3.7, 86.3) |
| ≥75 | 1 | 0.057 (250) | 2 | 0.048 (243) | 58.0 | (-706.0, 99.3) |
| 75-85 | 1 | 0.057 (249) | 2 | 0.047 (240) | 58.4 | (-699.8, 99.3) |
| Sex | | | | | | |
| Male | 26 | 0.531 (2256) | 83 | 0.470 (2305) | 72.3 | (56.5, 82.9) |
| Female | 37 | 0.567 (2383) | 65 | 0.463 (2296) | 53.6 | (29.5, 69.9) |
| Race | | | | | | |
| White | 57 | 0.863 (3708) | 121 | 0.737 (3698) | 59.8 | (44.4, 71.2) |
| Black or African American | 0 | 0.095 (360) | 14 | 0.080 (360) | 100.0 | (74.8, 100.0) |
| American Indian or Alaska Native | 4 | 0.019 (80) | 6 | 0.016 (87) | 41.9 | (-144.8, 87.9) |
| Asian | 2 | 0.062 (273) | 3 | 0.050 (257) | 46.9 | (-363.3, 95.6) |
| Multiracial | 0 | 0.053 (189) | 3 | 0.045 (174) | 100.0 | (-104.6, 100.0) |
| Not reported | 0 | 0.004 (22) | 1 | 0.003 (14) | 100.0 | (-2304.2, 100.0) |
| Ethnicity | | | | | | |

**Table 16. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination, by Subgroup – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population**

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4689) | | Placebo (N[a]=4664) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| Hispanic/Latino | 17 | 0.166 (679) | 25 | 0.146 (681) | 40.4 | (-14.9, 69.8) |
| Non-Hispanic/non-Latino | 46 | 0.930 (3951) | 123 | 0.785 (3912) | 68.4 | (55.4, 78.0) |
| Country | | | | | | |
| Brazil | 0 | 0.135 (517) | 10 | 0.133 (522) | 100.0 | (56.0, 100.0) |
| South Africa | 2 | 0.021 (74) | 2 | 0.023 (93) | -7.1 | (-1377.6, 92.2) |
| USA | 61 | 0.942 (4048) | 136 | 0.776 (3986) | 63.0 | (49.6, 73.1) |
| Time between Dose 2 and booster vaccination | | | | | | |
| ≥6 to <8 Months after Dose 2 | 14 | 0.143 (694) | 11 | 0.121 (674) | -7.3 | (-161.1, 54.8) |
| ≥8 to <10 Months after Dose 2 | 5 | 0.177 (734) | 31 | 0.159 (734) | 85.5 | (62.3, 95.6) |
| ≥10 to <12 Months after Dose 2 | 40 | 0.740 (3048) | 100 | 0.623 (3032) | 66.3 | (50.9, 77.3) |
| ≥12 Months after Dose 2 | 4 | 0.038 (163) | 6 | 0.029 (161) | 48.9 | (-115.6, 89.4) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster); SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants who had no serological or virological evidence (prior to 7 days after receipt of the booster vaccination) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visit 1, and had a negative NAAT [nasal swab] at any unscheduled visit prior to 7 days after booster vaccination) were included in the analysis.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 22MAR2022 (12:34)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubSIA/C4591031_A_SBLA/adc19ef_ve_cov_7d_wo_sg_eval_new

**Table 17. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination, by Risk Status – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population**

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4689) | | Placebo (N[a]=4664) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First COVID-19 occurrence from 7 days after booster vaccination | | | | | | |
| Overall | 63 | 1.098 (4639) | 148 | 0.932 (4601) | 63.9 | (51.1, 73.5) |
| At risk[f] | | | | | | |
| Yes | 37 | 0.527 (2219) | 74 | 0.447 (2220) | 57.6 | (36.3, 72.3) |
| No | 26 | 0.571 (2420) | 74 | 0.486 (2381) | 70.1 | (52.7, 81.7) |
| Age group (years) and at risk status | | | | | | |
| 16-64 and not at risk | 20 | 0.464 (1944) | 62 | 0.391 (1882) | 72.9 | (54.5, 84.5) |
| 16-64 and at risk | 35 | 0.383 (1683) | 69 | 0.328 (1615) | 56.5 | (33.7, 71.9) |
| ≥65 and not at risk | 6 | 0.107 (476) | 12 | 0.095 (499) | 55.4 | (-28.5, 86.3) |
| ≥65 and at risk | 2 | 0.144 (636) | 5 | 0.118 (605) | 67.3 | (-100.0, 96.9) |
| Obese[g] | | | | | | |
| Yes | 25 | 0.391 (1620) | 59 | 0.331 (1627) | 64.0 | (41.7, 78.4) |
| No | 38 | 0.707 (3017) | 89 | 0.601 (2974) | 63.7 | (46.4, 75.9) |
| Age group (years) and obesity status | | | | | | |
| 16-64 and not obese | 31 | 0.543 (2278) | 76 | 0.459 (2230) | 65.5 | (46.9, 78.0) |
| 16-64 and obese | 24 | 0.304 (1248) | 55 | 0.260 (1267) | 62.8 | (38.8, 78.0) |
| ≥65 and not obese | 7 | 0.165 (739) | 13 | 0.142 (744) | 53.7 | (-24.9, 84.4) |
| ≥65 and obese | 1 | 0.086 (372) | 4 | 0.072 (360) | 79.2 | (-110.4, 99.6) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster); SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants who had no serological or virological evidence (prior to 7 days after receipt of the booster vaccination) of past SARS-CoV-2 infection
(ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visit 1, and had a negative NAAT
[nasal swab] at any unscheduled visit prior to 7 days after the booster vaccination) were included in the analysis.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Includes participants who had at least 1 Charlson Comorbidity Index category or a BMI ≥30 kg/m$^2$.
g. Participants who had a BMI ≥30 kg/m$^2$.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 16MAR2022 (01:41)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_ve_cov_7d_wo_rg_eval

**Table 18. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination, by Comorbidity Status – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population**

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4689) | | Placebo (N[a]=4664) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First COVID-19 occurrence from 7 days after booster vaccination | | | | | | |
| Overall | 63 | 1.098 (4639) | 148 | 0.932 (4601) | 63.9 | (51.1, 73.5) |
| Comorbidity | | | | | | |
| No comorbidity | 26 | 0.571 (2420) | 74 | 0.486 (2381) | 70.1 | (52.7, 81.7) |
| Any comorbidity[f] | 37 | 0.527 (2219) | 74 | 0.447 (2220) | 57.6 | (36.3, 72.3) |
| Any malignancy | 4 | 0.054 (246) | 5 | 0.042 (214) | 38.1 | (-187.5, 87.7) |
| Cardiovascular | 3 | 0.037 (170) | 1 | 0.026 (134) | -113.3 | (-11096.6, 82.9) |
| Chronic pulmonary disease | 7 | 0.092 (405) | 17 | 0.084 (433) | 62.4 | (4.7, 86.8) |
| Diabetes | 8 | 0.096 (387) | 17 | 0.075 (379) | 63.2 | (10.0, 86.2) |
| Obese (≥30.0 kg/m$^2$) | 25 | 0.391 (1620) | 59 | 0.331 (1627) | 64.0 | (41.7, 78.4) |
| Hypertension | 16 | 0.300 (1268) | 39 | 0.254 (1262) | 65.3 | (36.4, 81.9) |
| Diabetes (including gestational diabetes) | 8 | 0.097 (390) | 17 | 0.075 (382) | 63.2 | (10.0, 86.3) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster); SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants who had no serological or virological evidence (prior to 7 days after receipt of the booster vaccination) of past SARS-CoV-2 infection
(ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visit 1, and had a negative NAAT
[nasal swab] at any unscheduled visit prior to 7 days after the booster vaccination) were included in the analysis.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Participant who had 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least 1 Charlson Comorbidity Index category or a BMI ≥30 kg/m$^2$.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 16MAR2022 (01:41)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_ve_cov_7d_wo_cg_eval

Additional data are presented in the following:

| | |
|---|---|
| Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination, by Subgroup – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population | Supplemental Table 14.29 |
| Vaccine Efficacy – First COVID-19 Occurrence After Booster Vaccination, by Subgroup – Blinded Follow-Up Period – All-Available Efficacy Population | Supplemental Table 14.30 |
| Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination, by Risk Status – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population | Supplemental Table 14.31 |
| Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination, by Comorbidity Status – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population | Supplemental Table 14.32 |

### 5.1.1.2. Updated Analysis of Secondary Efficacy Endpoints: Severe COVID-19

During the blinded follow-up period, in the evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days post-booster, there were 2 cases meeting severe criteria per the FDA definition (1 was previously reported in the 2-month analysis interim CSR, dated 18 November 2021) observed in the placebo group.

- The 2 cases in the placebo group occurred 22 and 84 days post-Dose 3, and both met the severe criterion of 'clinical signs at rest indicative of severe systemic illness' ($SpO_2$ ≤93% on room air at sea level).

In the all-available efficacy (mITT) population, 3 cases meeting severe criteria per the FDA definition were observed, all in the placebo group, which included the 2 cases in the evaluable efficacy population described above.

- The third case (previously reported in the 2-month analysis interim CSR, dated 18 November 2021) occurred 31 days post-Dose 3 (placebo) and also met the severe criterion of 'clinical signs at rest indicative of severe systemic illness' ($SpO_2$ ≤93% on room air at sea level).

All 3 severe cases (per FDA definition) occurred in participants who were baseline SARS-CoV-2 negative. Narratives were prepared for the severe cases.

No cases were reported that were based on CDC criteria for severe COVID-19.

Additional data are presented in the following:

| | |
|---|---|
| Case Narratives (severe COVID-19) | Section 14 |
| Vaccine Efficacy – First Severe COVID-19 Occurrence (Based on FDA Definition) From 7 Days After Booster Vaccination – Blinded Follow-up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population | Supplemental Table 14.33 |
| Vaccine Efficacy – First Severe COVID-19 Occurrence (Based on FDA Definition) From 7 Days After Booster Vaccination – Blinded Follow-up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population | Supplemental Table 14.34 |
| Vaccine Efficacy – First Severe COVID-19 Occurrence (Based on FDA Definition) From 7 Days After Booster Vaccination – Blinded Follow-up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – All-Available Efficacy Population | Supplemental Table 14.35 |
| Vaccine Efficacy – First Severe COVID-19 Occurrence (Based on FDA Definition) From 7 Days After Booster Vaccination – Blinded Follow-up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – All-Available Efficacy Population | Supplemental Table 14.36 |
| Vaccine Efficacy – First Severe COVID-19 Occurrence (Based on FDA Definition) After Booster Vaccination – Blinded Follow-up Period – All-Available Efficacy Population | Supplemental Table 14.37 |
| Listing of Participants With First Severe COVID-19 Occurrence (Based on FDA or CDC Definition) After Booster Vaccination – Blinded Follow-Up Period – All-Available Efficacy Population | Listing 16.2.8.2 |

### 5.1.2. Analysis of COVID-19 Incidences After BNT162b2 (Initially and Subsequently) – Blinded and Open-label Follow-up Period

#### 5.1.2.1. COVID-19 Cases

Analyses were performed for COVID-19 cases accrued when the Delta variant was the predominant strain (ie, during a defined time period beginning 27 September 2021 [first placebo crossover participant to receive BNT162b2 vaccination] through 19 December 2021) and when the Omicron variant was the predominant strain (ie, during a defined time period beginning 20 December 2021 through the data cutoff date of 08 February 2022). These analyses included data for participants ≥16 years of age and compared incidence rates for confirmed COVID-19 cases among 'early' versus 'late' vaccinees (ie, incidence was compared between participants who were randomized to receive BNT162b2 and thus received the vaccine at the beginning of the study [original group] versus participants who were randomized to placebo and later crossed over to BNT162b2 [crossover group]). BNT162b2 vaccination occurred in the early vaccine participants between 01 July 2021 and 10 August 2021 and in later vaccine participants between 27 September 2021 and 03 February 2022 (Appendix 16.1.7).

For cases of first COVID-19 occurrence from 27 September 2021 to 19 December 2021 (Delta variant wave), the IRs for later vaccinated participants (placebo crossover to

BNT162b2 group) and earlier vaccinated participants (original BNT162b2 group) were 31.159 and 38.136 per 1000 person-years of follow-up, respectively.

For cases of first COVID-19 occurrence from 20 December 2021 to 08 February 2022 (Omicron variant wave), the IRs for later vaccinated participants (placebo crossover to BNT162b2 group) and earlier vaccinated participants (original BNT162b2 group) were 576.808 and 990.327 per 1000 person-years of follow-up, respectively.

Kaplan-Meier curves show the case accrual from booster vaccination up to the data cutoff date for the later vaccinated participants (placebo crossover to BNT162b2 group) compared to the early vaccinated participants (original BNT162b2 group) and participants who received placebo (original placebo group), with severe COVID-19 cases denoted in with 'S' on the curves (Figure 2). Since these curves do not account for calendar time when participants were vaccinated, Figure 3 displays COVID-19 incidence over time for the 3 groups. This shows that the incidence rose dramatically from December 2021 (Appendix 16.2.8.4), when the highly transmissible Omicron variant became predominant.[14] Severe COVID-19 cases are discussed further in Section 5.1.1.2 (blinded follow-up period) and Section 5.1.2.2 (after unblinding).

Analysis of RVEs by date and IRs by time since BNT162b2 booster vaccination during the Omicron variant wave (20 December 2021 to the data cutoff date of 08 February 2022) together suggest waning vaccine against Omicron. For cases of first COVID-19 occurrence during Delta variant wave (27 September 2021 to 19 December 2021), the RVE in the later vaccinated participants (placebo crossover to BNT162b2 group) to that in the early vaccinated participants (original BNT162b2 group) was 18.3% (95% CI: -42.3%, 54.6%), based on 20 and 42 cases in later and early vaccinated participants, respectively. For cases of first COVID-19 occurrence during the Omicron variant wave, the RVE in the later vaccinated participants to that in the early vaccinated participants was 41.8% (95% CI: 33.2%, 49.3%), based on 323 and 603 cases in later and early vaccinated participants, respectively. During the Omicron variant wave, IR in the later vaccinated recipients (with <4 months since booster vaccination) was lower than in the early vaccine recipients (with ≥5 months since booster vaccination).

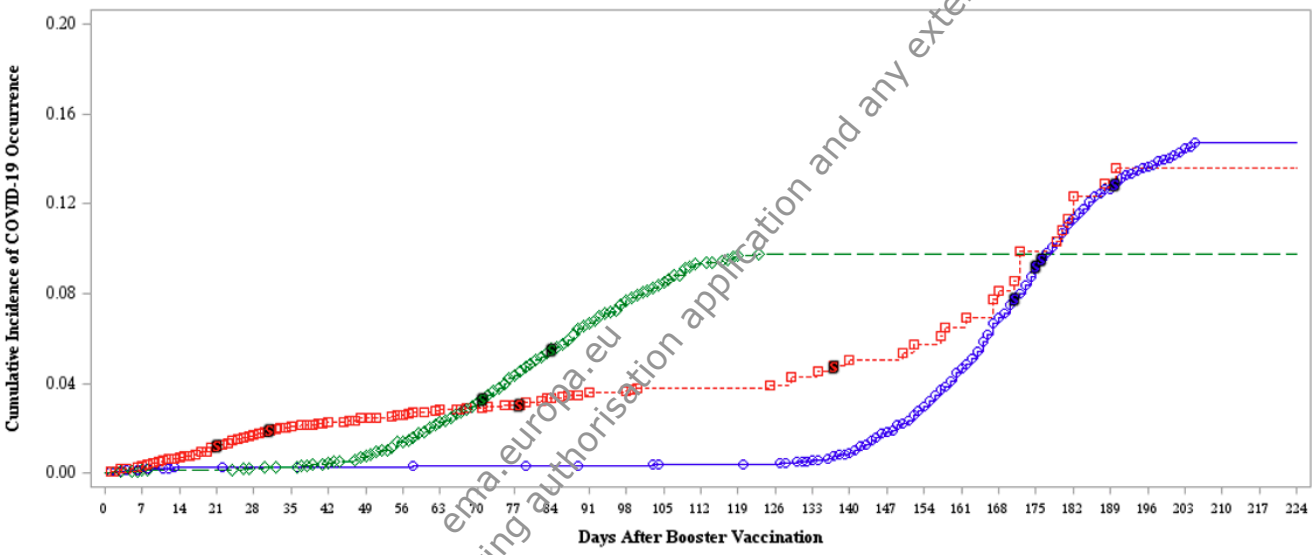
Taken together, this suggests a booster dose of BNT162b2 provides protection for both early and later vaccinated participants that is stronger during the time frame when Delta was the predominate variant compared to when Omicron was the predominant, and that vaccine efficacy against Omicron wanes with increasing time since BNT162b2 booster vaccination.

Additional data are presented in the following:

| | |
|---|---|
| Relative Vaccine Efficacy – First COVID-19 Occurrence After BNT162b2 Booster Vaccination From 27SEP2021 to 08FEB2022 – Participants Who Received BNT162b2 Booster Vaccination – All-Available Efficacy Population | Supplemental Table 14.38 |
| Incidence Rates of First COVID-19 Occurrence After BNT162b2 Booster Vaccination – Participants Who Received BNT162b2 Booster Vaccination – All-Available Efficacy Population | Supplemental Table 14.39 |

| | |
|---|---|
| Incidence Rates of First COVID-19 Occurrence After BNT162b2 Booster Vaccination From 20DEC2021 to 08FEB2022 by Time Since BNT162b2 Booster Vaccination – Participants Who Received BNT162b2 Booster Vaccination – All-Available Efficacy Population | Supplemental Table 14.40 |
| Listing of Participants With COVID-19 Occurrence After Unblinding – All-Available Efficacy Population | Listing 16.2.8.4 |

**Figure 2. Cumulative Incidence Curves for the First COVID-19 Occurrence After Booster Vaccination – All-Available Efficacy Population**




Participants at Risk

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A: | 4841 | 4833 | 4829 | 4829 | 4828 | 4825 | 4823 | 4822 | 4818 | 4814 | 4810 | 4806 | 4803 | 4799 | 4795 | 4790 | 4787 | 4784 | 4782 | 4775 | 4758 | 4714 | 4665 | 4579 | 4466 | 4356 | 4145 | 3699 | 2666 | 1506 | 274 | 8 | 0 |
| B: | 4925 | 4913 | 4893 | 4863 | 4830 | 4794 | 4775 | 4763 | 4738 | 4613 | 4310 | 3807 | 3133 | 2474 | 1966 | 1472 | 1025 | 711 | 562 | 449 | 366 | 293 | 260 | 241 | 222 | 204 | 175 | 146 | 99 | 51 | 9 | 0 | 0 |
| C: | 4284 | 4279 | 4275 | 4264 | 4245 | 4231 | 4216 | 4198 | 4131 | 4022 | 3895 | 3775 | 3570 | 3235 | 2723 | 2280 | 1779 | 1214 | 595 | 107 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |

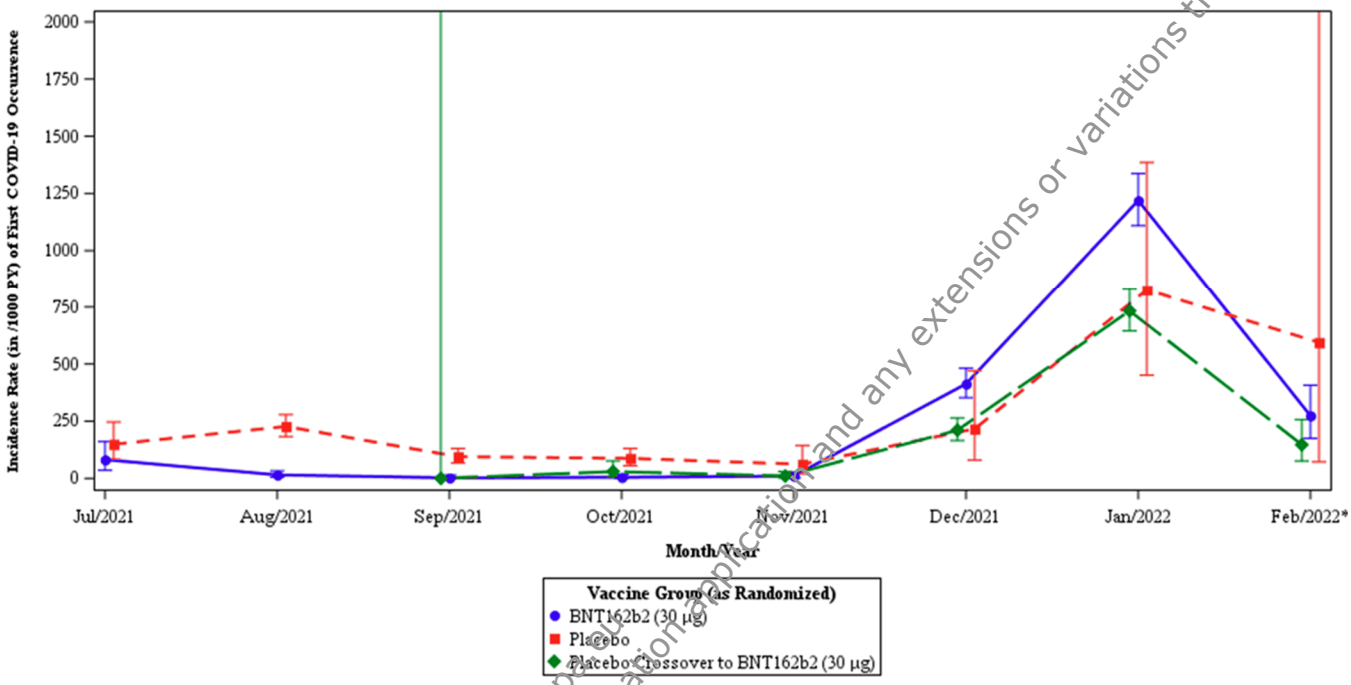
Cumulative Number of Events

| | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| A: | 0 | 8 | 12 | 12 | 13 | 13 | 14 | 14 | 14 | 15 | 15 | 15 | 16 | 17 | 17 | 19 | 19 | 19 | 20 | 28 | 44 | 88 | 142 | 224 | 333 | 442 | 541 | 602 | 638 | 656 | 659 | 659 | 659 |
| B: | 0 | 15 | 35 | 60 | 83 | 103 | 111 | 120 | 128 | 138 | 142 | 147 | 158 | 165 | 166 | 168 | 168 | 168 | 169 | 171 | 174 | 174 | 176 | 178 | 182 | 186 | 191 | 192 | 193 | 193 | 193 | 193 | 193 |
| C: | 0 | 5 | 6 | 6 | 9 | 11 | 18 | 32 | 60 | 95 | 130 | 179 | 224 | 264 | 297 | 319 | 336 | 342 | 343 | 343 | 343 | 343 | 343 | 343 | 343 | 343 | 343 | 343 | 343 | 343 | 343 | 343 | 343 |



Note: "S" indicates participants with severe COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adc19eu Table Generation: 16MAR2022 (09:20)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 18FEB2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA_RVE/adc19ef_f001_kmx_aai

**Figure 3. Incidence Rate of First COVID-19 Occurrence After Booster Vaccination, by Calendar Month - All-Available Efficacy Population**




Note: * Analysis for this month includes data from 01FEB2022 to data cutoff date of 08FEB2022.

Incidence rate (IR) is calculated as number of participants meeting the endpoint definition/total surveillance time (in 1000 person-years) across all participants at risk for the endpoint within the specific group for each calendar month.

Surveillance time period for COVID-19 case accrual for each calendar month begins at latest of BNT162b2 booster vaccination and the first day of the calendar month and ends at the earliest of confirmed case, death, withdrawn from the study, or end of the calendar month.

PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adc19eu Table Generation: 24MAR2022 (17:19)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 18FEB2022) Output File: /nda2_ubBIA/C4591031_A_SBLA_RVE/adc19eu_f001_lin_aai

#### 5.1.2.2. Severe COVID-19 Cases

After unblinding, in the all-available efficacy population there were 7 cases meeting severe criteria, 5 based on the FDA definition, 1 based on the CDC definition, and 1 based on both FDA and CDC definitions (Listing 16.2.8.5). All occurred after 20 December 2021 (start dates ranging from 31 December 2021 to 07 February 2022), when the Omicron variant was the predominant strain.

In original BNT162b2 participants, there were 5 cases meeting severe criteria (all in participants in the evaluable efficacy population with a first severe COVID-19 occurrence from 7 days after the booster vaccination and without evidence of infection prior to 7 days after the booster vaccination).

- In 3 participants, the cases met the FDA definition of severe (1 with $SpO_2$ ≤93% on room air at sea level, 2 with DBP <60 mm Hg) and occurred 176, 177, and 193 days post-booster.
- In 1 participant, the case met the CDC definition of severe (hospitalized due to COVID-19 illness) and occurred 166 days post-booster.
- In 1 participant, the case met the FDA and CDC definition of severe ($SpO_2$ ≤93% on room air at sea level, CPAP, hospitalized due to COVID-19 illness) and occurred 177 days post-booster.

In placebo participants who were unblinded and then received BNT162b2, there were 2 cases meeting severe criteria.

- In both participants, the cases met the FDA definition of severe (1 with DBP <60 mm Hg, 1 with SBP <90 mm Hg) and occurred 73 and 88 days post-booster.

All 7 severe cases occurred in participants who were baseline SARS-CoV-2 negative. Narratives were prepared for the severe cases.

### 5.2. Safety

Refer to the C4591031 Substudy A 2-Month Analysis Interim CSR, dated 18 November 2021, Section 5.2, for details of safety evaluations previously reported.

#### 5.2.1. Local Reactions and Systemic Events

The C4591031 safety endpoints for Substudy A did not include solicited reactogenicity (local reactions, systemic events) of BNT162b2 captured via e-diary. In Study C4591001, reactogenicity of BNT162b2 was typically mild to moderate and short-lived; further details for participants at least 16 years of age, as in this study, are provided in the C4591001 final analysis (03 December 2020), 6-month update (29 April 2021), and booster (Dose 3) (23 August 2021) interim CSRs.

### 5.2.2. Adverse Events

#### 5.2.2.1. Summary of Adverse Events

AE safety data are from either the blinded placebo-controlled follow-up period, the open-label observational follow-up period, or both. The time periods and safety analysis groups are presented below. Previously reported in the 2-month analysis interim CSR, dated 18 November 2021, were AEs during the blinded placebo-controlled follow-up period; this included AEs reported from booster vaccination (Visit 1) to 1 month after booster vaccination and from booster vaccination to the data cutoff date (05 October 2021), which represented up to at least 2 months post-booster follow-up. In this CSR, overall safety for each time period are presented in the following order:

- Blinded placebo-controlled follow-up period from booster vaccination to the unblinding date (Section 5.2.2.1.1);
- Open-label follow-up period – original BNT162b2 recipients (Section 5.2.2.1.2);
- Blinded placebo-controlled and open-label follow-up periods from booster vaccination to 6 months after booster vaccination – original BNT162b2 participants with at least 6 months follow-up (Section 5.2.2.1.3);
- Open-label follow-up period – original placebo recipients who then received BNT162b2 after unblinding (Section 5.2.2.1.4).

##### 5.2.2.1.1. Blinded Placebo-Controlled Follow-Up Period From Booster Vaccination to the Unblinding Date

###### 5.2.2.1.1.1. Overview of Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Booster Vaccination to the Unblinding Date

An overview of AEs from booster vaccination to the unblinding date for participants during the blinded placebo-controlled follow-up period is shown in Table 19. Note that, as there was no use of an electronic diary to record local reactions or systemic events, all such events were reported as AEs.

A greater proportion of participants in the BNT162b2 (26.4%) experienced any AE compared with the placebo group (7.8%). This was driven primarily by any AEs considered by the investigator as related to study intervention, reported in 23.9% participants in the BNT162b2 group and 4.2% participants in the placebo group. Any severe AEs or SAEs were reported across the BNT162b2 and placebo groups in ≤1.1% and ≤0.8%, respectively.

AEs leading to withdrawal were reported in 1 participant in the placebo group (life-threatening SAEs of metastatic cancer with renal, diaphragm, and hepatic involvement, previously reported in the 2-month analysis interim CSR dated 18 November 2021, Section 5.2.2.4), and none in the BNT162b2 group. During this period, 2 participants in the placebo group died due to unrelated SAEs (discussed in Section 5.2.2.2).

**Table 19. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date – Blinded Follow-Up Period – Safety Population**

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 1335 | 26.4 (25.2, 27.6) | 102.3 | (96.9, 108.0) | 394 | 7.8 (7.1, 8.6) | 34.8 | (31.5, 38.5) |
| Related[g] | 1206 | 23.9 (22.7, 25.1) | 92.5 | (87.3, 97.8) | 213 | 4.2 (3.7, 4.8) | 18.9 | (16.4, 21.6) |
| Severe | 55 | 1.1 (0.8, 1.4) | 4.2 | (3.2, 5.5) | 34 | 0.7 (0.5, 0.9) | 3.0 | (2.1, 4.2) |
| Life-threatening | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 6 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) |
| Any serious adverse event | 39 | 0.8 (0.5, 1.1) | 3.0 | (2.1, 4.1) | 35 | 0.7 (0.5, 1.0) | 3.1 | (2.2, 4.3) |
| Related[g] | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Severe | 23 | 0.5 (0.3, 0.7) | 1.8 | (1.1, 2.6) | 26 | 0.5 (0.3, 0.8) | 2.3 | (1.5, 3.4) |
| Life-threatening | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 6 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) |
| Any nonserious adverse event | 1313 | 26.0 (24.8, 27.2) | 100.7 | (95.3, 106.3) | 377 | 7.5 (6.8, 8.3) | 33.4 | (30.1, 36.9) |
| Related[g] | 1204 | 23.8 (22.6, 25.0) | 92.3 | (87.2, 97.7) | 213 | 4.2 (3.7, 4.8) | 18.9 | (16.4, 21.6) |
| Severe | 36 | 0.7 (0.5, 1.0) | 2.8 | (1.9, 3.8) | 11 | 0.2 (0.1, 0.4) | 1.0 | (0.5, 1.7) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Severe | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Death | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (20:21)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s092_all_6m_saf

#### 5.2.2.1.1.1.1. Subgroup Analyses

A subgroup analysis of AE overviews from booster vaccination to the unblinding date for participants during the blinded placebo-controlled follow-up period is provided below. Further subgroup analyses of AEs by SOC and PT are provided in Section 5.2.2.1.1.2.1.

**Age, Sex, Race, Ethnicity, Country, and Baseline Status**

*Age*

The frequency of any AE after BNT162b2 booster vaccination was 28.6% in the younger (16 to 55 years of age) group and 23.6% in the older (>55 years of age) group. Related AEs were reported in the BNT162b2 groups at a higher frequency in younger (26.9%) compared to older (20.1%) groups (with numerical differences driven by reactogenicity events in these subgroups). Low incidences of severe and serious AEs were reported in the BNT162b2 groups in the younger (≤0.9%) and older (≤1.4%) groups. The small numerical differences were not considered clinically meaningful.

*Sex*

The frequency of any AE after BNT162b2 booster vaccination was 23.3% in male participants and 29.4% in female participants. Related AEs were reported in the BNT162b2 group by 20.7% of male participants and 26.8% of female participants (with numerical differences driven by reactogenicity events in these subgroups). Low incidences of severe and serious AEs were reported in the BNT162b2 groups in male participants (≤0.9%) and female participants (≤1.3%). The small numerical differences were not considered clinically meaningful.

*Race*

The frequency of any AE after BNT162b2 booster vaccination was 25.0% to 36.6% across race subgroups. Related AEs were reported in the BNT162b2 group across race subgroups at frequencies of 22.3% to 35.0%. Low incidences of severe and serious AEs were reported in the BNT162b2 groups across race subgroups (≤1.2%). Taking into account that some race subgroups had fewer participants than others (within the BNT162b2 groups: White N=3986, Black or African American N=457, and 'All Others' N=612), the small numerical differences were not considered clinically meaningful.

*Ethnicity*

The frequency of any AE after BNT162b2 booster vaccination was 37.3% in Hispanic/Latino participants and 24.5% in non-Hispanic/non-Latino participants. Related AEs were reported in the BNT162b2 group by 35.8% of Hispanic/Latino participants and 21.7% of non-Hispanic/non-Latino participants (with numerical differences driven by reactogenicity events in these subgroups). Low incidences of severe and serious AEs were reported in the BNT162b2 groups in Hispanic/Latino participants (≤0.4%) and non-Hispanic/non-Latino participants (≤1.2%). Taking into account that among BNT162b2 recipients, the Hispanic/Latino subgroup (N=757) had fewer participants than non-Hispanic/non-Latino subgroup (N=4286), the small numerical differences were not considered clinically meaningful.

*Country*

The frequency of any AE after BNT162b2 booster vaccination varied between the countries, taking into account that few participants were enrolled in Brazil and South Africa compared to the US; however, the pattern of differences observed between BNT162b2 and placebo groups

was similar across the country subgroups and similar to the overall safety population (including most reported AEs being reactogenicity events). In order of increasing frequency, any AEs were reported by country as follows: South Africa, 6.5%; US, 21.0%; and Brazil 71.4% (note that participants in Brazil contributed to the Hispanic/Latino subgroup described above). Related AEs made up most of the reported AEs in frequencies similar to the reporting of any AEs across country subgroups (5.7% to 70.9%). Low incidences of severe and serious AEs were reported in the BNT162b2 groups across country subgroups (≤1.2%). Given the variable enrollment by country (within the BNT162b2 groups: N=123 in South Africa, N=580 in Brazil, and N=4352 in the US), the numerical differences were not considered clinically meaningful.

*Baseline SARS-CoV-2 Status*

The frequency of any AE after BNT162b2 booster vaccination was 25.1% in baseline SARS-CoV-2 positive participants (N=283) and 26.5% in baseline SARS-CoV-2 negative participants (N=4765). Related AEs were reported in similar frequencies of the BNT162b2 groups of baseline positive participants (23.7%) and baseline negative participants (23.9%). Low incidences of severe and serious AEs were reported in the BNT162b2 groups in baseline positive (≤0.4%) and baseline negative participants (≤1.1%). The small numerical differences were not considered clinically meaningful.

**HIV-Positive Participants**

The AE overviews from booster vaccination to the unblinding date in HIV-positive participants (N=26 in the BNT162b2 group and N=24 in the placebo group) included fewer reported AEs relative to the overall safety population. The frequency of any AE after booster vaccination was 1 participant (3.8%) in the BNT162b2 group and 1 participant (4.2%) in the placebo group among HIV-positive participants. These AEs were non-serious, non-severe, and reported as related to study intervention.

Additional data are presented in the following:

| | |
|---|---|
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.41-14.42 |
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.43-14.44 |
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.45-14.47 |
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.48-14.50 |
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.51-14.53 |

| | |
|---|---|
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.54-14.55 |
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date - Blinded Follow-Up Period – HIV-Positive Participants – Safety Population | Supplemental Table 14.56 |

#### 5.2.2.1.1.2. Adverse Events by System Organ Class and Preferred Term – Blinded Placebo-Controlled Follow-Up Period From Booster Vaccination to the Unblinding Date

AEs reported from booster vaccination to the unblinding date for participants during the blinded placebo-controlled follow-up period are presented by SOC and PT in Supplemental Table 14.57. Any AEs were reported at a higher frequency in the BNT162b2 group (26.4%) than the placebo group (7.8%). Most AEs reported during this period reflect reactogenicity events (ie, injection site pain, fatigue, myalgia, pyrexia, and headache), which account for the imbalance between groups. AE frequencies in SOCs containing reactogenicity terms in the BNT162b2 versus placebo groups were:

- general disorders and administration site conditions: 21.4% vs 3.2%
- musculoskeletal and connective tissue disorders: 7.0% vs 1.1%
- nervous system disorders: 5.9% vs 1.4%
- gastrointestinal disorders: 1.8% vs 0.9%

Overall, most AEs reported in the BNT162b2 group were largely attributable to reactogenicity and similar types of events that suggest reactogenicity (ie, fatigue [7.4%], chills [4.7%], injection site pain [13.0%], pyrexia [5.0%]) as well as events reflecting lymphadenopathy (axillary pain [0.3%], lymph node pain [0.1%], and lymphadenopathy [2.7%]). This is consistent with the AE profile previously observed following Dose 2 of the initial two-dose regimen. Notably, lymphadenopathy was reported at a higher frequency in C4591031 participants post-booster vaccination with BNT162b2 (2.7%) compared with participants in C4591001 after the two-dose primary series of BNT162b2 (0.4%). Lymphadenopathy is thought to be related to development of vaccine-elicited immune responses.

AEs of clinical interest are detailed in Section 5.2.2.5, which include those considered by the FDA as AESIs, those designated by the CDC as AESIs associated with COVID-19, and other AEs identified by sponsor review of the study safety database. One case of Bell's palsy was identified in a placebo booster recipient, 4 events of unrelated appendicitis (including appendicitis and appendicitis perforated [n=2 each]) were identified in BNT162b2 booster recipients, and a summary of lymphadenopathy events (most of which were considered booster-related) are summarized in the AESI section, as well as evaluation of any numerical imbalance between CDC designated AESIs or other events of clinical interest between BNT162b2 and placebo groups.

#### 5.2.2.1.1.2.1. Subgroup Analyses

A subgroup analysis of AEs by SOC and PT from booster vaccination to the unblinding date for participants during the blinded placebo-controlled follow-up period is provided below.

**Age, Sex, Race, Ethnicity, Country, and Baseline Status**

*Age*

The AE profiles in the younger (16 to 55 years of age) and older (>55 years of age) adult groups were similar to the overall safety population. Most AEs reported in each age group were in SOCs that capture reactogenicity events, which occurred more frequently in the BNT162b2 groups compared to the placebo groups. The frequency of lymphadenopathy after BNT162b2 booster dose administration was 4.0% in the younger group and 1.0% in the older group. Numerical differences between most SOCs/PTs were not considered clinically meaningful.

*Sex*

The AE profiles in male and female participants were similar to the overall safety population. Most AEs reported in each sex subgroup were in SOCs that capture reactogenicity events, which occurred more frequently in the BNT162b2 groups compared to the placebo groups; among BNT162b2 recipients, reactogenicity events were more frequently reported in female versus male participants:

- general disorders and administration site conditions: 24.0% vs 18.6%
- musculoskeletal and connective tissue disorders: 7.8% vs 6.2%
- nervous system disorders: 7.3% vs 4.4%
- gastrointestinal disorders: 2.2% vs 1.4%

The frequency of reported lymphadenopathy after BNT162b2 booster dose administration was 1.8% in male participants and 3.5% in female participants.

*Race*

The AE profiles in race subgroups were similar to the overall safety population. Most AEs reported in each race subgroup were in SOCs that capture reactogenicity events, which occurred more frequently in the BNT162b2 groups compared to the placebo groups. The frequency of lymphadenopathy after BNT162b2 booster dose administration was 2.4% in White participants, 2.8% in Black or African American participants, and 4.1% for 'All Other' race subgroups. Numerical differences between most SOCs/PTs were not considered clinically meaningful.

*Ethnicity*

The AE profiles in ethnicity subgroups were similar to the overall safety population. Most AEs reported in each ethnicity subgroup were in SOCs that capture reactogenicity events, which occurred more frequently in the BNT162b2 groups compared to the placebo groups;

among BNT162b2 recipients, reactogenicity events were more frequently reported in Hispanic/Latino versus non-Hispanic/non-Latino participants:

- general disorders and administration site conditions: 32.6% vs 19.4%
- musculoskeletal and connective tissue disorders: 8.9% vs 6.7%
- nervous system disorders: 7.3% vs 5.6%
- gastrointestinal disorders: 1.7% vs 1.8%

The frequency of reported lymphadenopathy after BNT162b2 booster dose administration was 3.8% in Hispanic/Latino participants and 2.5% in non-Hispanic/non-Latino participants.

*Country*

The AE profiles in country subgroups were similar to the overall safety population. Most AEs reported in each country subgroup were in SOCs that capture reactogenicity events, which occurred more frequently in the BNT162b2 groups compared to the placebo groups. The frequency of lymphadenopathy after BNT162b2 booster dose administration was 1.9% in participants in the US, 4.1% in participants in South Africa, and 7.9% in participants in Brazil. Numerical differences between most SOCs/PTs were not considered clinically meaningful.

*Baseline SARS-CoV-2 Status*

The AE profiles after BNT162b2 booster vaccination in baseline SARS-CoV-2 positive (N=283) and negative (N=4765) participants were similar to the overall safety population. Most AEs reported in each baseline status group were in SOCs that capture reactogenicity events, which occurred more frequently in the BNT162b2 groups compared to the placebo groups. The frequency of lymphadenopathy after BNT162b2 booster dose administration was 1.8% in baseline positive participants and 2.7% in baseline negative participants. Numerical differences between most SOCs/PTs were not considered clinically meaningful.

**HIV-Positive Participants**

Among HIV-positive participants (N=26 in the BNT162b2 group and N=24 in the placebo group), only reactogenicity events (fatigue, pain, and headache) were reported in 1 participant each in the BNT162b2 group (3.8%) and the placebo group (4.2%).

Additional data are presented in the following:

| | |
|---|---|
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.57 |
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.58-14.59 |

| | |
|---|---|
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.60-61 |
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.62-64 |
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.65-67 |
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.68-70 |
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.71-72 |
| Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term - Blinded Follow-Up Period – HIV-Positive Participants – Safety Population | Supplemental Table 14.73 |

#### 5.2.2.1.1.3. Related Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Booster Vaccination to the Unblinding Date

From booster vaccination to the unblinding date for participants during the blinded placebo-controlled follow-up period, AEs assessed by the investigator as related to study intervention were reported more frequently in the BNT162b2 group (23.9%) than in the placebo group (4.2%). Most related AEs were reactogenicity events (ie, injection site pain, fatigue, myalgia, pyrexia, and headache), most commonly in the SOC of general disorders and administration site conditions reported in 21.3% of participants in the BNT162b2 group and 3.0% of participants in the placebo group.

Other than events in SOCs that capture reactogenicity events, lymphadenopathy considered by the investigator as related to study intervention was the most common related AE, reported in 134 participants (2.7%) in the BNT162b2 group and by 1 participant (0.0%) in the placebo group. Lymphadenopathy is analyzed further in Section 5.2.2.5.

No events in the immune system disorders SOC were reported as related to BNT162b2.

In both the younger (16 to 55 years of age) and older (>55 years of age) age groups, most related AEs reported (26.9% and 20.1%, respectively) were in SOCs that capture reactogenicity events. The frequencies of related AEs of lymphadenopathy were 4.0% in the younger group and 1.0% in the older group. Small numerical differences between most SOCs/PTs were not considered clinically meaningful.

Additional data are presented in the following:

| | |
|---|---|
| Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Table 14.74 |
| Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.75-76 |

#### 5.2.2.1.1.4. Immediate Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Booster Vaccination to the Unblinding Date

These results were previously reported in the 2-month analysis interim CSR dated 18 November 2021.

The frequencies of immediate AEs (occurring within 30 minutes post-vaccination) reported after the booster dose were low (≤0.3%) and similar across the BNT162b2 and placebo groups.

Immediate events after booster vaccination with BNT162b2 were predominantly reactogenicity events (ie, injection site pain, injection site erythema, injection site swelling, pyrexia, and headache). One participant in the BNT162b2 group reported immediate dizziness.

Immediate events after receipt of placebo included reactogenicity events (ie, injection site pain, fatigue, headache) and immediate events of nausea, oral paresthesia, chest discomfort, heart rate increased, arthralgia, musculoskeletal discomfort, paresthesia, cold sweat, and flushing.

No immediate allergic reactions to BNT162b2 booster administration were observed.

There was no clinical meaningful difference between the younger group (16 to 55 years of age) and older group (>55 years of age) with regard to the reported immediate AEs post-booster.

#### 5.2.2.1.1.5. Severe and Life-Threatening Adverse Events – Blinded Placebo-Controlled Follow-Up Period From Booster Vaccination to the Unblinding Date

From booster vaccination to the unblinding date for participants during the blinded placebo-controlled follow-up period, severe events were reported in 55 participants (1.1%) in the BNT162b2 group and 34 participants (0.7%) in the placebo group. The higher frequency of severe events in the BNT162b2 group was mostly due to severe reactogenicity events (ie, fatigue, pyrexia, injection site pain, myalgia, and headache).

Life-threatening (or Grade 4) events were reported in 4 participants (0.1%) in the BNT162b2 group and 6 participants (0.1%) in the placebo group. These were reported as SAEs (Section 5.2.2.3). One event was assessed as related by the investigator: acute myocardial infarction, reported in the placebo group (Appendix 16.2.7.4).

There was no clinically meaningful difference between the younger group (16 to 55 years of age) and older group (>55 years of age) with regard to the reported severe AEs post-booster. The few reported life-threatening AEs were reported exclusively in the older group (>55 years of age).

Additional data are presented in the following:

| | |
|---|---|
| Incidence Rates of at Least 1 Severe Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Table 14.77 |
| Incidence Rates of at Least 1 Severe Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.78-14.79 |
| Incidence Rates of at Least 1 Life-Threatening Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Table 14.80 |
| Incidence Rates of at Least 1 Life-Threatening Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.81-14.82 |

#### 5.2.2.1.2. Open-Label Follow-Up Period From the Unblinding Date to the Data Cutoff Date – Original BNT162b2 Recipients

##### 5.2.2.1.2.1. Overview of Adverse Events – Open-Label Follow-Up Period From the Unblinding Date to the Data Cutoff Date – Original BNT162b2 Recipients

An overview of AEs from the unblinding date to the data cutoff date for participants who originally received BNT162b2 during the open-label follow-up period is presented in Table 20. (Note: Per protocol, AEs are reported through 1 month after booster vaccination and within 48 hours after a blood draw. SAEs are reported to 6 months after the last dose of study intervention.)

There were 74 participants (1.6%) who experienced any AE, including 0.4%, and 0.2% who experienced severe, and life-threatening events, respectively (Table 20). No related events were reported. This is markedly reduced relative to AEs from booster vaccination to the unblinding date (26.4% of BNT162b2 participants experienced any AE, including 23.9%, 1.1%, and 0.1% who experienced related, severe, and life-threatening events, respectively [Table 19]). The frequencies of participants with any SAE and any AE leading to withdrawal during the open-label follow-up period (0.8% and 0.0% [1 participant, assessed as unrelated], respectively [Table 20]) were similar to those from booster vaccination to the unblinding date (0.8% and 0%, respectively [Table 19]). During this period, 3 participants died due to unrelated SAEs (discussed in Section 5.2.2.2).

**Table 20. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to the Cutoff Date – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population**

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4489, TE[b]=14.2) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 74 | 1.6 (1.3, 2.1) | 5.2 | (4.1, 6.5) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Severe | 17 | 0.4 (0.2, 0.6) | 1.2 | (0.7, 1.9) |
| Life-threatening | 9 | 0.2 (0.1, 0.4) | 0.6 | (0.3, 1.2) |
| Any serious adverse event | 36 | 0.8 (0.6, 1.1) | 2.5 | (1.8, 3.5) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Severe | 17 | 0.4 (0.2, 0.6) | 1.2 | (0.7, 1.9) |
| Life-threatening | 9 | 0.2 (0.1, 0.4) | 0.6 | (0.3, 1.2) |
| Any nonserious adverse event | 45 | 1.0 (0.7, 1.3) | 3.2 | (2.3, 4.2) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Severe | 2 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.5) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Any adverse event leading to withdrawal | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Severe | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Life-threatening | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Death | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.6) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from unblinding date to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (20:56)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBLA/C4591031_A_SBLA/adae_s092_cut_bnt_ol_saf

During the open-label follow-up period, the frequency of any AE after BNT162b2 booster vaccination was 1.5% in the younger (16 to 55 years of age) group and 1.8% in the older (>55 years of age) group (Supplemental Tables 14.83 and 14.84). None of the reported AEs were assessed as related.

**HIV-Positive Participants**

From the unblinding date to the data cutoff date for participants who originally received BNT162b2 during the open-label follow-up period, no HIV-positive participants reported any AEs (Listings 16.2.7.2 and 16.1.7).

### 5.2.2.1.2.2. Adverse Events by System Organ Class and Preferred Term – Open-Label Follow-Up Period From the Unblinding Date to the Data Cutoff Date – Original BNT162b2 Recipients

From the unblinding date to the data cutoff date (open-label follow-up period) for participants who originally received BNT162b2, the frequency of participants who reported at least 1 AE was 1.6% compared to 26.4% from booster vaccination to the unblinding date (Table 19).

Overall, the rates in all SOCs after the unblinding date were lower or remained similar to those in the blinded placebo-controlled period.

The SOC with the highest frequency of reported events was infections and infestations (14 participants [0.3%]), with each PT reported in 1 participant each except for cellulitis (3 participants), followed by the SOC of neoplasms benign, malignant and unspecified (including cysts and polyps) (10 participants [0.2%]), with each PT reported in 1 participant each.

AEs of clinical interest are detailed in Section 5.2.2.5, which include those considered by the FDA as AESIs, those designated by the CDC as AESIs associated with COVID-19, and other AEs identified by sponsor review of the study safety database. The AESI section summarizes events during this period, which occurred in ≤2 participants each.

The AE profiles in the younger (16 to 55 years of age) and older (>55 years of age) adult groups were similar to the overall safety population. In the younger group, the SOCs with the highest frequency of AEs reported were infections and infestations (8 [0.3%]) and gastrointestinal disorders (5 [0.2%]), with each PT in those SOCs reported in 1 participant each. In the older group, the SOCs with the highest frequency of AEs reported were infections and infestations (6 [0.3%]) and general disorders and administration site conditions (3 [0.2%]), with each PT in those SOCs reported in 1 participant each except for cellulitis (3 participants). Numerical differences between most SOCs/PTs were not considered clinically meaningful.

Additional data are presented in the following:

| | |
|---|---|
| Incidence Rates of at Least 1 Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population | Supplemental Table 14.85 |
| Incidence Rates of at Least 1 Adverse Event From Unblinding Date to the Cutoff Date, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population | Supplemental Tables 14.86-14.87 |

#### 5.2.2.1.2.3. Related Adverse Events – Open-Label Follow-Up Period From the Unblinding Date to the Data Cutoff Date – Original BNT162b2 Recipients

From the unblinding date to the data cutoff date (open-label follow-up period) for participants who originally received BNT162b2, none of the AEs were assessed as related by the investigator (Table 20).

#### 5.2.2.1.2.4. Severe and Life-Threatening Adverse Events – Open-Label Follow-Up Period From the Unblinding Date to the Data Cutoff Date – Original BNT162b2 Recipients

From the unblinding date to the data cutoff date (open-label follow-up period), 17 BNT162b2 participants (0.4%) experienced severe AEs. All severe AEs were reported in 1 participant each; the SOCs with the highest frequency of AEs reported was gastrointestinal disorders (5 participants).

From the unblinding date to the data cutoff date (open-label follow-up period), there were 5 (0.2%) BNT162b2 participants who had at least 1 life-threatening AE. These were reported as SAEs (Section 5.2.2.3). None of the life-threatening AEs reported during this period were assessed by the investigator as related to study intervention (Appendix 16.2.7.4).

There were no clinical meaningful difference between the younger group (16 to 55 years of age) and older group (>55 years of age) with regard to the reported severe or life-threatening AEs post-booster; the few events reported were experienced by 1 participant each in both age groups.

Additional data are presented in the following:

| | |
|---|---|
| Incidence Rates of at Least 1 Severe Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population | Supplemental Table 14.88 |
| Incidence Rates of at Least 1 Severe Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population | Supplemental Tables 14.89-14.90 |
| Incidence Rates of at Least 1 Life-Threatening Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population | Supplemental Table 14.91 |
| Incidence Rates of at Least 1 Life-Threatening Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population | Supplementals Tables 14.92-14.93 |

#### 5.2.2.1.3. Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Booster Vaccination to 6 Months After Booster Vaccination – Original BNT162b2 Recipients

##### 5.2.2.1.3.1. Overview of Adverse Events – Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Booster Vaccination to 6 Months After Booster Vaccination – Original BNT162b2 Recipients

There were 5000 participants who originally received BNT162b2 and had at least 6 months of follow-up time after booster vaccination for the blinded placebo-controlled and open-label follow-up periods (Table 21). In total, 27.3% participants experienced at least 1 AE, and those assessed as related were reported in 24.0%. Any severe AEs or SAEs were reported in 1.4% and 1.3%, respectively.

For these participants, AEs leading to withdrawal were reported in 1 participant due to an unrelated SAE (discussed in Section 5.2.2.4) and 1 participant died due to an unrelated SAE (discussed in Section 5.2.2.2).

**Table 21. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population**

| Adverse Event | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5000)<br>n[b] (%) |
|---|---|
| Any adverse event | 1366 (27.3) |
| Related[c] | 1199 (24.0) |
| Severe | 69 (1.4) |
| Life-threatening | 10 (0.2) |
| Any serious adverse event | 67 (1.3) |
| Related[c] | 3 (0.1) |
| Severe | 38 (0.8) |
| Life-threatening | 10 (0.2) |
| Any nonserious adverse event | 1331 (26.6) |
| Related[c] | 1197 (23.9) |
| Severe | 38 (0.8) |
| Life-threatening | 0 |
| Any adverse event leading to withdrawal | 1 (0.0) |
| Related[c] | 0 |
| Severe | 0 |
| Life-threatening | 1 (0.0) |
| Death | 1 (0.0) |

**Table 21. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population**

| | Vaccine Group (as Administered) |
|---|---|
| Adverse Event | BNT162b2 (30 µg) (N[a]=5000) n[b] (%) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (09:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s091_all_6m_3k_saf

For participants with at least 6 months follow-up time after BNT162b2 booster vaccination, the frequency of any AE post-booster was 29.4% in the younger (16 to 55 years of age) group and 24.7% in the older (>55 years of age) group (Supplemental Tables 14.94 and 14.95). Related AEs were reported in the BNT162b2 group by 27.0% in the younger group and 20.3% in the older group. Low incidences of severe and serious AEs were reported in the BNT162b2 groups in the younger (≤1.1%) and older (≤1.7%) groups. Small numerical differences were not considered clinically meaningful.

### 5.2.2.1.3.2. Adverse Events by System Organ Class and Preferred Term – Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Booster Vaccination to 6 Months After Booster Vaccination – Original BNT162b2 Recipients

There were 1366 participants (27.3%) who originally received BNT162b2, had at least 6 months of follow-up time after booster vaccination, and reported AEs from the time of booster vaccination to 6 months post-booster. Frequently reported AEs included reactogenicity events in the following SOCs:

- general disorders and administration site conditions: 21.6%
- musculoskeletal and connective tissue disorders: 7.2%
- nervous system disorders: 6.0%
- blood and lymphatic system disorders: 2.9%

Overall, most AEs reported were largely attributable to reactogenicity and similar types of events that suggest reactogenicity (ie, injection site pain [13.1%], fatigue [7.4%], pyrexia [5.0%], chills [4.7%], pain [2.7%], and pain in extremity [1.1%]) as well as events reflective of lymphadenopathy (axillary pain [0.3%], lymph node pain [0.1%], and lymphadenopathy [2.7%]). This is consistent with the AE profile previously observed following Dose 2 of the initial two-dose regimen. Notably, lymphadenopathy was reported at a higher frequency in

C4591031 participants post-booster vaccination with BNT162b2 (2.7%) compared with participants in C4591001 after the two-dose primary series of BNT162b2 (0.4%). Lymphadenopathy is thought to be related to development of vaccine-elicited immune responses.

AEs of clinical interest are detailed in Section 5.2.2.5, which include those considered by the FDA as AESIs, those designated by the CDC as AESIs associated with COVID-19, and other AEs identified by sponsor review of the study safety database. The AESI section summarizes events in participants who originally received BNT162b2 and entered the unblinded period, including those who had at least 6 months of follow-up time post-booster.

The AE profiles in the younger (16 to 55 years of age) and older (>55 years of age) adult groups were similar to the overall safety population. In both the younger and older age groups, the 2 SOCs with the highest frequency of AEs reported were general disorders and administration site conditions (24.1% and 18.5%, respectively) and musculoskeletal and connective tissue disorders (7.7% and 6.5%, respectively). Lymphadenopathy was reported in 4.0% of participants in the younger age group and 1.0% of participants in the older age group. Overall, numerical differences between most SOCs/PTs were not considered clinically meaningful.

Additional data are presented in the following:

| | |
|---|---|
| Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster | Supplemental Table 14.96 |
| Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster | Supplemental Tables 14.97-14.98 |

#### 5.2.2.1.3.3. Related Adverse Events – Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Booster Vaccination to 6 Months After Booster Vaccination – Original BNT162b2 Recipients

From booster vaccination to 6 months post-booster, 1199 original BNT162b2 recipients (24.0%) experienced AEs assessed by the investigator as related to study intervention. Most related AEs were reactogenicity events and in the SOCs of general disorders and administration site conditions, musculoskeletal and connective tissue disorders, and nervous system disorders, reported in 21.4% participants, 6.4% participants, and 5.6% participants, respectively. Related events of lymphadenopathy were reported in 133 participants (2.7%) who originally received BNT162b2 and had at least 6 months of follow-up time post-booster (refer to other significant AEs in Section 5.2.2.5).

In participants who originally received BNT162b2 and had at least 6 months of follow-up time post-booster, 27.0% in the younger (16 to 55 years of age) group and 20.3% in the older (>55 years of age) group experienced AEs assessed by the investigator as related to study

intervention. The AE profiles in both age groups were similar to the overall safety population, with most AEs in SOCs that capture reactogenicity events. The frequency of lymphadenopathy after BNT162b2 booster dose administration was 4.0% in the younger group and 1.0% in the older group. Numerical differences between most SOCs/PTs were not considered clinically meaningful.

Additional data are presented in the following:

| | |
|---|---|
| Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population | Supplemental Table 14.99 |
| Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population | Supplemental Tables 14.100-14.101 |

#### 5.2.2.1.4. Open-Label Follow-Up Period from BNT162b2 Vaccination to the Data Cutoff Date – Original Placebo Recipients Who Then Received BNT162b2 After Unblinding

##### 5.2.2.1.4.1. Overview of Adverse Events – Open-Label Follow-Up Period from Visit 101 BNT162b2 Vaccination to the Data Cutoff Date – Original Placebo Recipients Who Then Received BNT162b2 After Unblinding

An overview of AEs for 4396 original placebo recipients who then were unblinded and received BNT162b2 (at Visit 101) to the data cutoff date during the open-label follow-up period is presented in Table 22.

The AE profile of original placebo recipients who then were unblinded and received BNT162b2 (Table 22) was similar to those who originally received BNT162b2 (Table 19). The proportion of original placebo recipients who then were unblinded and received BNT162b2 who experienced any AE was 19.3%, which was driven primarily by any AEs considered by the investigator as related to study intervention (17.4%) (Table 22). Any severe AEs or SAEs were reported in 0.4% and 0.4% of participants, respectively.

During the open-label follow-up period after Visit 101, AEs leading to withdrawal were reported in 3 participants due to unrelated SAEs (discussed in Section 5.2.2.4), and 4 participants died due to unrelated SAEs (discussed in Section 5.2.2.2).

Of note, 1 event of COVID-19 pneumonia (unrelated, severe) was reported as an SAE, and the SAE was subsequently invalidated as the event met the case criteria for efficacy analyses. Refer to the Errata for further details.

**Table 22. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population**

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 847 | 19.3 (18.1, 20.5) | 67.0 | (62.5, 71.6) |
| Related[g] | 765 | 17.4 (16.3, 18.6) | 60.5 | (56.3, 64.9) |
| Severe | 17 | 0.4 (0.2, 0.6) | 1.3 | (0.8, 2.2) |
| Life-threatening | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.9) |
| Any serious adverse event | 19 | 0.4 (0.3, 0.7) | 1.5 | (0.9, 2.3) |
| Related[g] | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Severe | 6 | 0.1 (0.1, 0.3) | 0.5 | (0.2, 1.0) |
| Life-threatening | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.9) |
| Any nonserious adverse event | 831 | 18.9 (17.8, 20.1) | 65.7 | (61.3, 70.3) |
| Related[g] | 764 | 17.4 (16.3, 18.5) | 60.4 | (56.2, 64.8) |
| Severe | 11 | 0.3 (0.1, 0.4) | 0.9 | (0.4, 1.6) |
| Life-threatening | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Any adverse event leading to withdrawal | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Severe | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Life-threatening | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Death | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:15)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s092_cut_ol_saf

In original placebo recipients who then were unblinded and received BNT162b2, the frequency of any AE after BNT162b2 booster vaccination was 21.1% in the younger (16 to 55 years of age) group and 16.9% in the older (>55 years of age) group. Related AEs were reported in 19.8% in the younger group and 14.4% in the older group. Low incidences of severe and serious AEs were reported in the younger (≤0.3%) and older (≤0.7%) groups.

Small numerical differences between the younger and older age groups were not considered clinically meaningful.

**HIV-Positive Participants**

In original placebo recipients who then were unblinded and received BNT162b2, the AE overviews after BNT162b2 booster vaccination in HIV-positive participants (N=23) included fewer reported AEs relative to the overall safety population. The frequency of any AE was 6 participants (26.1%) among HIV-positive participants. These AEs were non-serious, non-severe, and reported as related to study intervention.

Additional data are presented in the following:

| | |
|---|---|
| Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population | Supplemental Tables 14.102-14.103 |
| Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – HIV-Positive Participants – Safety Population | Supplemental Table 14.104 |

**5.2.2.1.4.2. Adverse Events by System Organ Class and Preferred Term – Open-Label Follow-Up Period from Visit 101 BNT162b2 Vaccination to the Data Cutoff Date – Original Placebo Recipients Who Then Received BNT162b2 After Unblinding**

From vaccination with BNT162b2 (at Visit 101) for placebo participants to the data cutoff date (open-label follow-up period), 847 participants (19.3%) experienced at least 1 AE.

Most AEs reported after booster vaccination with BNT162b2 to the data cutoff date were in SOCs with reactogenicity events.

- general disorders and administration site conditions: 15.7%
- musculoskeletal and connective tissue disorders: 3.6%
- nervous system disorders: 3.5%
- gastrointestinal disorders: 1.1%

Overall, most AEs reported were largely attributable to reactogenicity and similar types of events that suggest reactogenicity (ie, injection site pain [9.0%], fatigue [4.9%], headache [3.1%], pyrexia [3.0%], pain [2.8%], myalgia [2.4%], and chills [2.3%]) as well as events of reflecting lymphadenopathy (ie, axillary pain [0.3%], lymph node pain [0.1%] and lymphadenopathy [1.3%]).

The AE profiles in the younger (16 to 55 years of age) and older (>55 years of age) age groups were similar to the overall safety population. Most AEs reported in each age group were in SOCs that capture reactogenicity events. The frequency of lymphadenopathy after BNT162b2 booster dose administration was 1.8% in the younger group and 0.7% in the older

group. For the 2 age groups, numerical differences between most SOCs/PTs were not considered clinically meaningful.

AEs of clinical interest are detailed in Section 5.2.2.5, which include those considered by the FDA as AESIs, those designated by the CDC as AESIs associated with COVID-19, and other AEs identified by sponsor review of the study safety database. The AESI section summarizes events during this period.

Of note, 1 event of COVID-19 pneumonia (unrelated, severe) was reported as an SAE, and the SAE was subsequently invalidated as the event met the case criteria for efficacy analyses. Refer to the Errata for further details.

Additional data are presented in the following:

| | |
|---|---|
| Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population | Supplemental Table 14.105 |
| Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population | Supplemental Tables 14.106-14.107 |

#### 5.2.2.1.4.3. Related Adverse Events – Open-Label Follow-Up Period from Visit 101 BNT162b2 Vaccination to the Data Cutoff Date – Original Placebo Recipients Who Then Received BNT162b2 After Unblinding

From vaccination with BNT162b2 (at Visit 101) to the data cutoff date (open-label follow-up period) for original placebo recipients who then received BNT162b2 after unblinding, 765 participants (17.4%) experienced AEs that were assessed as related by the investigator. Most related AEs were reactogenicity events (ie, injection site pain, fatigue, myalgia, pyrexia, and headache), most commonly in the SOC of general disorders and administration site conditions reported in 15.5% of participants.

Other than events in SOCs that capture reactogenicity events, lymphadenopathy considered by the investigator as related to study intervention was the most common related AE, reported in 56 participants (1.3%). Lymphadenopathy is analyzed further in Section 5.2.2.5.

No events in the immune system disorders SOC were reported as related to BNT162b2. One nonserious event of periorbital oedema, assessed as related, was reported in a participant in the younger age group (16 to 55 years) with an onset at Day 2 and reported as resolved/recovered within 1 day (Appendix 16.2.7.2).

In both the younger (16 to 55 years of age) and older (>55 years of age) age groups, related AEs were reported in 19.8% and 14.4% of participants, respectively, and most related AEs reported were in SOCs that capture reactogenicity events. The frequencies of related AEs of

lymphadenopathy were 1.8% in the younger group and 0.7% in the older group. For the 2 age groups, small numerical differences between most SOCs/PTs were not considered clinically meaningful.

Additional data are presented in the following:

| | |
|---|---|
| Incidence Rates of at Least 1 Related Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population | Supplemental Table 14.108 |
| Incidence Rates of at Least 1 Related Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population | Supplemental Tables 14.109-14.110 |

#### 5.2.2.1.4.4. Immediate Adverse Events – Open-Label Follow-Up Period from Visit 101 BNT162b2 Vaccination to the Data Cutoff Date – Original Placebo Recipients Who Then Received BNT162b2 After Unblinding

From vaccination with BNT162b2 (at Visit 101) to the data cutoff date (open-label follow-up period) for original placebo recipients who then received BNT162b2 after unblinding, 8 participants (0.2%) reported immediate AEs after BNT162b2 booster vaccination. Most immediate AEs were reported in 1 participant each, except for injection site pain in 5 participants (0.1%).

No allergic AEs were reported after BNT162b2 within 30 minutes after vaccination.

There was no clinically meaningful difference between the younger group (16 to 55 years of age) and older group (>55 years of age) with regard to the reported immediate AEs post-booster.

Additional data are presented in the following:

| | |
|---|---|
| Number (%) of Participants Reporting at Least 1 Immediate Adverse Event After BNT162b2 Booster Vaccination, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population | Supplemental Table 14.111 |
| Number (%) of Participants Reporting at Least 1 Immediate Adverse Event After BNT162b2 Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population | Supplemental Tables 14.112-14.113 |

#### 5.2.2.1.4.5. Severe and Life-Threatening Adverse Events – Open-Label Follow-Up Period from Visit 101 BNT162b2 Vaccination to the Data Cutoff Date – Original Placebo Recipients Who Then Received BNT162b2 After Unblinding

From vaccination with BNT162b2 (at Visit 101) to the data cutoff date (open-label follow-up period) for original placebo recipients who then received BNT162b2 after unblinding, severe events were reported in 17 participants (0.4%). Most events were due to severe reactogenicity events, and most were reported in 1 participant each except for headache (5 [0.1%]), pyrexia (2 [0.0%]), and myalgia (2 [0.0%]).

Life-threatening (or Grade 4) events were reported in 5 participants (0.1%) after BNT162b2 booster vaccination. These were reported as SAEs (Section 5.2.2.3). None of the life-threatening AEs reported during this period were assessed by the investigator as related to study intervention (Appendix 16.2.7.4).

There was no clinically meaningful difference between the younger group (16 to 55 years of age) and older group (>55 years of age) with regard to the reported severe or life-threatening AEs after BNT162b2 booster vaccination.

Of note, 1 event of COVID-19 pneumonia (unrelated, severe) was reported as an SAE, and the SAE was subsequently invalidated as the event met the case criteria for efficacy analyses. Refer to the Errata for further details.

Additional data are presented in the following:

| | |
|---|---|
| Incidence Rates of at Least 1 Severe Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population | Supplemental Table 14.114 |
| Incidence Rates of at Least 1 Severe Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population | Supplemental Tables 14.115-14.116 |
| Incidence Rates of at Least 1 Life-Threatening Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population | Supplemental Table 14.117 |
| Incidence Rates of at Least 1 Life-Threatening Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population | Supplemental Tables 14.118-14.119 |

#### 5.2.2.2. Deaths

In total, there were 9 participants who died during the study as of the data cutoff date, including 3 in the younger (16-55 years) and 6 in the older (>55 years) age groups (Appendix 16.2.7.6). Narratives for these events are provided in Section 14. None of these deaths were assessed by the investigator as related to study intervention (Appendices 16.2.7.2 and 16.2.7.4).

During the blinded placebo-controlled follow-up period, 2 participants in the placebo group died (and no participants in the BNT162b2 group died). One placebo participant had an unrelated SAE of pulmonary embolism (reported in Section 5.2.2.2 of the 2-month analysis interim CSR, dated 18 November 2021), and one participant with PPD had an unrelated SAE of pneumocystis jirovecii pneumonia.

From the unblinding date to the data cutoff date of the open-label follow-up period, there were:

- 3 deaths in original BNT162b2 participants, due to unrelated events of myocardial infarction, infection, and death (of unknown causes).
- 4 deaths in original placebo participants who then received BNT162b2, due to unrelated events of multiple injuries (received in a car accident), ill-defined disorder (death of unknown causes), adrenocortical carcinoma (with metastasis; SAE), and sudden cardiac death.

For the original BNT162b2 participant (40 years of age) with an unrelated myocardial infarction with onset at Day 147 post-booster that resulted in death on Day 157 post-booster, the participant also reported at Day 137 post-booster an unrelated AE of hemorrhagic shock (severe, SAE), discussed in Section 5.2.2.3.2, and unrelated AEs of GI hemorrhage (severe), hepatomegaly (mild), and seizure (mild). Medical history included a past PPD (Appendix 16.2.5.3). Further details are provided in the narrative in Section 14.

#### 5.2.2.3. Serious Adverse Events

##### 5.2.2.3.1. Blinded Placebo-Controlled Follow-Up Period From Booster Vaccination to the Unblinding Date

From booster vaccination to the unblinding date for participants during the blinded placebo-controlled follow-up period, there were 39 BNT162b2 participants (0.8%) and 35 placebo participants (0.7%) who reported at least 1 SAE (Table 23). Most of these SAEs were assessed by the investigator as not related to study intervention (Table 19). In the BNT162b2 group, the SOC with the highest frequency (>0.1%) of AEs reported was infections and infestations (8 participants [0.2%]).

SAEs were assessed as related for 5 participants (3 in the BNT162b2 group and 2 in the placebo group; Appendix 16.2.7.4). Narratives were prepared for each event (Section 14), and all were previously described in detail in Section 5.2.2.3 of the 2-month analysis interim CSR, dated 18 November 2021: tachycardia (n=1, BNT162b2), increased hepatic enzymes (n=2, BNT162b2), acute myocardial infarction (n=1, placebo), and chest pain (n=1, placebo).

One participant who received placebo had an unrelated SAE of COVID-19 pneumonia that did not meet case criteria to be included in the efficacy analyses (described in Section 5.2.2.3 of the 2-month analysis interim CSR, dated 18 November 2021).

Additionally, the following unrelated SAEs were reported during the blinded follow-period and are included with the AESIs in Section 5.2.2.5: pericarditis (n=1, placebo), appendicitis (n=2, BNT162b2), appendicitis perforated (n=1, BNT162b2), and septic shock (n=1, BNT162b2) (Appendix 16.2.7.2).

**Table 23. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population**

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 39 | 0.8 (0.5, 1.1) | 3.0 | (2.1, 4.1) | 35 | 0.7 (0.5, 1.0) | 3.1 | (2.2, 4.3) |
| Cardiac disorders | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Acute myocardial infarction | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Atrial fibrillation | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cardiac failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pericarditis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Tachycardia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Endocrine disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Goitre | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Gastrointestinal disorders | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Gastric fistula | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| General disorders and administration site conditions | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Chest discomfort | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hepatobiliary disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Bile duct stone | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Immune system disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Food allergy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## Table 23. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Infections and infestations | 8 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.2) | 7 | 0.1 (0.1, 0.3) | 0.6 | (0.2, 1.3) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Appendicitis | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Appendicitis perforated | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Device related infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Diverticulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Empyema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Salmonellosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Sepsis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Septic shock | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Urinary tract infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injury, poisoning and procedural complications | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hip fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Humerus fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ligament rupture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Stoma complication | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Investigations | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hepatic enzyme increased | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Musculoskeletal and connective tissue disorders | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Back pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

## Table 23. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 6 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.0) | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Prostate cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nervous system disorders | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Syncope | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pregnancy, puerperium and perinatal conditions | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abortion spontaneous | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Psychiatric disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Renal and urinary disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Nephrolithiasis | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Renal cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Reproductive system and breast disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 7 | 0.1 (0.1, 0.3) | 0.6 | (0.2, 1.3) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

**Table 23. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population**

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pleural effusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Respiratory failure | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Vascular disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hypertension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 01APR2022 (02:56)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_t131_ser_all_6m_saf

#### 5.2.2.3.1.1.1. Subgroup Analyses

A subgroup analysis of SAEs from booster vaccination to the unblinding date for participants during the blinded, placebo-controlled follow-up period is provided below.

**Age, Sex, Race, Ethnicity, Country, and Baseline Status**

*Age*

A slightly higher frequency of SAEs was reported in the older (>55 years) age groups for BNT162b2 and placebo recipients (1.1% vs 0.9%) compared with the younger (16 to 55 years) age groups (0.5% vs 0.5%), without any clinically meaningful imbalance between BNT162b2 and placebo booster recipients within each age group.

*Sex*

The frequencies of SAEs were similar in male BNT162b2 and placebo recipients (0.9% vs 0.8%) compared with female recipients (0.7% vs 0.6%), without any clinically meaningful imbalance between BNT162b2 and placebo booster recipients within each sex subgroup.

*Race*

The frequencies of SAEs were similar across the race subgroups for BNT162b2 (0.4% to 0.9%) and placebo recipients (0.7% for each subgroup), without any clinically meaningful imbalance between BNT162b2 and placebo booster recipients within each race subgroup.

*Ethnicity*

The frequencies of SAEs were similar in Hispanic/Latino BNT162b2 and placebo recipients (0.4% vs 0.8%) compared with non-Hispanic/non-Latino recipients (0.8% vs 0.7%), without any clinically meaningful imbalance between BNT162b2 and placebo booster recipients within each ethnicity subgroup.

*Country*

Given the variable enrollment by country, there were no SAEs reported from participants in South Africa for either vaccine group. After BNT162b2 booster vaccination, the frequencies of SAEs were similar in the US and Brazil (0.8% vs 0.9%). After placebo, the frequencies of SAEs were similar in the US and Brazil (0.7% vs 0.9%). There was no clinically meaningful imbalance between BNT162b2 and placebo recipients within country subgroups.

*Baseline SARS-CoV-2 Status*

No SAEs were reported in the BNT162b2 group among baseline SARS-CoV-2 positive participants (N=283) compared to a total of 3 SAEs reported in the placebo group. Among baseline negative participants in the BNT162b2 group (N=4769), the SAE frequency (0.8%) was similar to the placebo group (0.7%) and the overall safety population.

**HIV-Positive Participants**

No HIV-positive participants reported any SAEs (Listings 16.2.7.2, 16.2.7.4, and 16.1.7).

Additional data are presented in the following:

| | |
|---|---|
| Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.120-14.121 |
| Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.122-14.123 |
| Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.124-126 |
| Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Tables 14.127-129 |
| Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Table 14.130-132 |
| Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Table 14.133-134 |

#### 5.2.2.3.2. Open-Label Follow-Up Period From the Unblinding Date to the Data Cutoff Date – Original BNT162b2 Recipients

From unblinding date to the data cutoff date, 36 original BNT162b2 participants (0.8%) experienced at least 1 SAE (Table 24); none were assessed by the investigator as related (Table 20). All SAEs were reported in 1 participant each; the SOCs with the highest frequency (>0.1%) of AEs reported were infections and infestations (7 participants [0.2%]) and neoplasms benign, malignant and unspecified (including cysts and polyps) (7 participants [0.2%]).

The unrelated SAEs of chest pain (n=1) and appendicitis (n=1) are included with the AESIs in Section 5.2.2.5, and the unrelated SAE of hemorrhagic shock (n=1) occurred in a participant with a myocardial infarction of fatal outcome (further discussed in Section 5.2.2.2).

The SAE profiles in the younger (16 to 55 years of age) and older (>55 years of age) adult groups were similar to the overall safety population (Supplemental Tables 14.135 and 136).

**Table 24. Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population**

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4489, TE[b]=14.2) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 36 | 0.8 (0.6, 1.1) | 2.5 | (1.8, 3.5) |
| Blood and lymphatic system disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Sickle cell anaemia with crisis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Cardiac disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Acute myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Atrial fibrillation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Gastrointestinal disorders | 6 | 0.1 (0.0, 0.3) | 0.4 | (0.2, 0.9) |
| Colitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Gastrointestinal haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Hiatus hernia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Intestinal perforation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Lower gastrointestinal haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pancreatic pseudocyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pancreatitis acute | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| General disorders and administration site conditions | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Chest pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Death | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Non-cardiac chest pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Infections and infestations | 7 | 0.2 (0.1, 0.3) | 0.5 | (0.2, 1.0) |
| Appendicitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Cellulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Gastroenteritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Liver abscess | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Lyme disease | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Osteomyelitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Peritonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injury, poisoning and procedural complications | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Clavicle fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Craniocerebral injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Subdural haematoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Metabolism and nutrition disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Hypervolaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Musculoskeletal and connective tissue disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Arthralgia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

**Table 24. Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population**

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4489, TE[b]=14.2) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 7 | 0.2 (0.1, 0.3) | 0.5 | (0.2, 1.0) |
| Brain neoplasm | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Breast cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Meningioma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nervous system neoplasm | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Prostate cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Uterine cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nervous system disorders | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.7) |
| Cerebral haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Seizure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Syncope | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Psychiatric disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Bipolar disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Renal and urinary disorders | 2 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.5) |
| End stage renal disease | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Negative pressure pulmonary oedema | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Vascular disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Shock haemorrhagic | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from unblinding date to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (07:56)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_cut_sae_bnt_ol_saf

#### 5.2.2.3.3. Blinded Placebo-Controlled and Open-Label Follow-Up Periods From Booster Vaccination to 6 Months After Booster Vaccination – Original BNT162b2 Recipients

From booster vaccination to 6 months after booster vaccination, during the blinded placebo-controlled and open-label follow-up periods, 67 participants who originally received BNT162b2 (1.3%) reported at least 1 SAE (Table 25). The SOCs with the highest frequency (>0.1%) of AEs reported were infections and infestations (13 participants [0.3%]) and neoplasms benign, malignant and unspecified (including cysts and polyps) (13 participants [0.3%]). There were 3 SAE assessed as related, which occurred during the blinded follow-up period (Section 5.2.2.3.1) and were previously described in detail in the 2-month analysis interim CSR.

The SAE profiles in the younger (16 to 55 years of age) and older (>55 years of age) adult groups were similar to the overall safety population (Supplemental Tables 14.137 and 138). Numerical differences between most SOCs/PTs were not considered clinically meaningful.

**Table 25. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=5000)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Any event | 67 (1.3) | (1.0, 1.7) |
| Blood and lymphatic system disorders | 1 (0.0) | (0.0, 0.1) |
| Sickle cell anaemia with crisis | 1 (0.0) | (0.0, 0.1) |
| Cardiac disorders | 7 (0.1) | (0.1, 0.3) |
| Acute myocardial infarction | 3 (0.1) | (0.0, 0.2) |
| Atrial fibrillation | 3 (0.1) | (0.0, 0.2) |
| Cardiac failure | 1 (0.0) | (0.0, 0.1) |
| Myocardial infarction | 1 (0.0) | (0.0, 0.1) |
| Tachycardia | 1 (0.0) | (0.0, 0.1) |
| Endocrine disorders | 1 (0.0) | (0.0, 0.1) |
| Goitre | 1 (0.0) | (0.0, 0.1) |
| Gastrointestinal disorders | 7 (0.1) | (0.1, 0.3) |
| Colitis | 1 (0.0) | (0.0, 0.1) |
| Gastric fistula | 1 (0.0) | (0.0, 0.1) |
| Hiatus hernia | 1 (0.0) | (0.0, 0.1) |
| Intestinal perforation | 1 (0.0) | (0.0, 0.1) |
| Lower gastrointestinal haemorrhage | 1 (0.0) | (0.0, 0.1) |

**Table 25. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=5000)<br>n[b] (%) | (95% CI[c]) |
|---|---|---|
| Pancreatic pseudocyst | 1 (0.0) | (0.0, 0.1) |
| Pancreatitis acute | 1 (0.0) | (0.0, 0.1) |
| Small intestinal obstruction | 1 (0.0) | (0.0, 0.1) |
| General disorders and administration site conditions | 3 (0.1) | (0.0, 0.2) |
| Chest discomfort | 1 (0.0) | (0.0, 0.1) |
| Death | 1 (0.0) | (0.0, 0.1) |
| Non-cardiac chest pain | 1 (0.0) | (0.0, 0.1) |
| Immune system disorders | 1 (0.0) | (0.0, 0.1) |
| Food allergy | 1 (0.0) | (0.0, 0.1) |
| Infections and infestations | 13 (0.3) | (0.1, 0.4) |
| Appendicitis | 3 (0.1) | (0.0, 0.2) |
| Abdominal sepsis | 1 (0.0) | (0.0, 0.1) |
| Appendicitis perforated | 1 (0.0) | (0.0, 0.1) |
| Cellulitis | 1 (0.0) | (0.0, 0.1) |
| Cholangitis infective | 1 (0.0) | (0.0, 0.1) |
| Device related infection | 1 (0.0) | (0.0, 0.1) |
| Diverticulitis | 1 (0.0) | (0.0, 0.1) |
| Gastroenteritis | 1 (0.0) | (0.0, 0.1) |
| Liver abscess | 1 (0.0) | (0.0, 0.1) |
| Lyme disease | 1 (0.0) | (0.0, 0.1) |
| Osteomyelitis | 1 (0.0) | (0.0, 0.1) |
| Peritonitis | 1 (0.0) | (0.0, 0.1) |
| Salmonellosis | 1 (0.0) | (0.0, 0.1) |
| Septic shock | 1 (0.0) | (0.0, 0.1) |
| Injury, poisoning and procedural complications | 7 (0.1) | (0.1, 0.3) |
| Acetabulum fracture | 1 (0.0) | (0.0, 0.1) |
| Clavicle fracture | 1 (0.0) | (0.0, 0.1) |
| Craniocerebral injury | 1 (0.0) | (0.0, 0.1) |
| Humerus fracture | 1 (0.0) | (0.0, 0.1) |
| Ligament rupture | 1 (0.0) | (0.0, 0.1) |
| Pelvic fracture | 1 (0.0) | (0.0, 0.1) |
| Stoma complication | 1 (0.0) | (0.0, 0.1) |
| Subdural haematoma | 1 (0.0) | (0.0, 0.1) |
| Investigations | 2 (0.0) | (0.0, 0.1) |
| Hepatic enzyme increased | 2 (0.0) | (0.0, 0.1) |

**Table 25. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population**

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5000) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Metabolism and nutrition disorders | 1 (0.0) | (0.0, 0.1) |
| Hypervolaemia | 1 (0.0) | (0.0, 0.1) |
| Musculoskeletal and connective tissue disorders | 5 (0.1) | (0.0, 0.2) |
| Arthralgia | 1 (0.0) | (0.0, 0.1) |
| Back pain | 1 (0.0) | (0.0, 0.1) |
| Intervertebral disc protrusion | 1 (0.0) | (0.0, 0.1) |
| Intervertebral disc space narrowing | 1 (0.0) | (0.0, 0.1) |
| Osteoarthritis | 1 (0.0) | (0.0, 0.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 13 (0.3) | (0.1, 0.4) |
| Invasive ductal breast carcinoma | 2 (0.0) | (0.0, 0.1) |
| Prostate cancer | 2 (0.0) | (0.0, 0.1) |
| Acute lymphocytic leukaemia | 1 (0.0) | (0.0, 0.1) |
| Brain neoplasm | 1 (0.0) | (0.0, 0.1) |
| Breast cancer | 1 (0.0) | (0.0, 0.1) |
| Follicular lymphoma | 1 (0.0) | (0.0, 0.1) |
| Meningioma | 1 (0.0) | (0.0, 0.1) |
| Nervous system neoplasm | 1 (0.0) | (0.0, 0.1) |
| Ovarian cancer | 1 (0.0) | (0.0, 0.1) |
| Renal cell carcinoma | 1 (0.0) | (0.0, 0.1) |
| Uterine cancer | 1 (0.0) | (0.0, 0.1) |
| Nervous system disorders | 7 (0.1) | (0.1, 0.3) |
| Syncope | 3 (0.1) | (0.0, 0.2) |
| Cerebrovascular accident | 2 (0.0) | (0.0, 0.1) |
| Cerebral haemorrhage | 1 (0.0) | (0.0, 0.1) |
| Toxic encephalopathy | 1 (0.0) | (0.0, 0.1) |
| Pregnancy, puerperium and perinatal conditions | 2 (0.0) | (0.0, 0.1) |
| Abortion spontaneous | 2 (0.0) | (0.0, 0.1) |
| Psychiatric disorders | 1 (0.0) | (0.0, 0.1) |
| Suicidal ideation | 1 (0.0) | (0.0, 0.1) |
| Renal and urinary disorders | 5 (0.1) | (0.0, 0.2) |
| Nephrolithiasis | 3 (0.1) | (0.0, 0.2) |
| End stage renal disease | 1 (0.0) | (0.0, 0.1) |
| Renal cyst | 1 (0.0) | (0.0, 0.1) |
| Respiratory, thoracic and mediastinal disorders | 1 (0.0) | (0.0, 0.1) |

**Table 25. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population**

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5000) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Acute respiratory failure | 1 (0.0) | (0.0, 0.1) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (13:12)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_ser_all_om_3k.saf

### 5.2.2.3.4. Open-Label Follow-Up Period from Visit 101 BNT162b2 Vaccination to the Data Cutoff Date – Original Placebo Recipients Who Then Received BNT162b2 After Unblinding

From vaccination with BNT162b2 (Visit 101) to the data cutoff date (open-label follow-up period) for original placebo recipients who then received BNT162b2 after unblinding, 19 participants (0.4%) experienced at least 1 SAE after BNT162b2 booster vaccination (Table 26). The SOC with the highest frequency of AEs reported was infections and infestations (5 participants [0.1%] participants). Two SAEs were assessed as related to the investigational product, described below (Appendices 16.2.5.3, 16.2.7.2, and 16.2.7.4) and further detailed in the narratives in Section 14:

- A participant in the older (>55 years) age group had a moderate event of COPD that was assessed as related. The event onset was 3 days post booster, and the outcome was reported as recovered/resolved within 16 days of onset. This participant had no other reported AEs, and the ongoing medical history included PPD .
- A participant in the older (>55 years) age group had a severe event of cellulitis (on the left arm, in which the vaccine was administered) that was assessed as related. The event onset was 41 days post booster, and the outcome was reported as recovered/resolved within 66 days of onset. This participant had also reported AEs of headache (2 days post booster, assessed as related) and diabetes mellitus exacerbation (assessed as not related; ongoing medical history included PPD ).

One participant in the older (>55 years) age group had an unrelated, severe event of COVID-19 pneumonia that was reported as an SAE. (The event onset was 29 days post booster, and it was reported as resolved within 16 days of onset. This participant had no other reported AEs, and no relevant ongoing medical history.) The SAE was subsequently invalidated as the event met the case criteria for efficacy analyses. Refer to the Errata for further details.

The SAE profiles in the younger (16 to 55 years of age) and older (>55 years of age) adult groups were similar to the overall safety population (Supplemental Tables 14.139 and 14.140). Numerical differences between most SOCs/PTs were not considered clinically meaningful.

**Table 26. Incidence Rates of at Least 1 Serious Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population**

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 19 | 0.4 (0.3, 0.7) | 1.5 | (0.9, 2.3) |
| Cardiac disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Atrial fibrillation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Gastrointestinal disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Pancreatitis acute | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Small intestinal obstruction | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| General disorders and administration site conditions | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Death | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Sudden cardiac death | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Infections and infestations | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.9) |
| COVID-19 pneumonia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Cellulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Diverticulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pneumonia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Urinary tract infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injury, poisoning and procedural complications | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Femur fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Multiple injuries | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Road traffic accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Musculoskeletal and connective tissue disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Arthralgia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

**Table 26. Incidence Rates of at Least 1 Serious Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population**

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Osteoarthritis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Adrenocortical carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Biliary neoplasm | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Chronic obstructive pulmonary disease | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Vascular disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Deep vein thrombosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (07:56)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_cut_sae_ol_saf

### 5.2.2.4. Discontinuations from Study Intervention or Study Due to Adverse Events

In total, there were 6 booster recipients with any AE leading to withdrawal, as of the data cutoff date, and 1 additional participant who was screened, presented with an AE an unrelated AE of presyncope and failed screening, but was later re-screened and then received a booster dose of BNT162b2 (Appendix 16.2.7.5). None of the events were assessed as related. These events are also included in the SAE analysis (Section 5.2.2.3), and narratives were prepared for the 6 events leading to withdrawal (Section 14).

During the blinded placebo-controlled follow-up period, AEs resulted in withdrawal from the study for 1 participant in the placebo group with unrelated, life-threatening SAEs of

metastatic cancer with renal, diaphragm, and hepatic involvement (reported in Section 5.2.2.4 of the 2-month analysis interim CSR, dated 18 November 2021).

From the unblinding date to the data cutoff date of the open-label follow-up period, there were:

- 1 withdrawal from the study in original BNT162b2 participants, due to an unrelated death (Section 5.2.2.2).
- 3 withdrawals from the study in original placebo participants who then received BNT162b2, due to 2 unrelated deaths and 1 unrelated, fatal event of adrenocortical carcinoma (with metastasis) (Section 5.2.2.2).
- 1 withdrawal (from study intervention) in an original placebo participant (who did not subsequently receive BNT162b2 after unblinding), due to an unrelated event of precancerous cells (present on nose). (The participant was later withdrawn from the study due to a PD of receipt of a nonstudy coronavirus vaccine [Appendix 16.2.2]).

Additional data are presented in the following:

| | |
|---|---|
| Incidence Rates of Participants Withdrawn Because of Adverse Events From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population | Supplemental Table 14.141 |
| Incidence Rates of Participants Withdrawn Because of Adverse Events From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population | Supplemental Table 14.142 |
| Incidence Rates of Participants Withdrawn Because of Adverse Events From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population | Supplemental Table 14.143 |

### 5.2.2.5. Other Significant Adverse Events

Adverse events of specific clinical interest, such as those requested by the FDA and those on the CDC list of AESIs for COVID-19, were reviewed based on AEs reported up to the cutoff date (08 February 2022). Narratives (Section 14) were prepared for AEs of clinical interest/AESIs if reported in the study safety database as of the data cutoff date. AEs of clinical interest are summarized below (Listings 16.2.7.2, 16.2.7.4, 16.1.7, 16.2.4, and 16.2.5.3) for reported events up to the data cutoff date, which represents at least 6 months of follow-up after booster dose administration in 5000 participants originally randomized to BNT162b2.

### 5.2.2.5.1. FDA-Requested Adverse Events of Clinical Interest

No cases of anaphylaxis or hypersensitivity were reported in either group in Study C4591031 from booster vaccination to up to the data cutoff date (08 February 2022). Other events that were reported in the safety database are summarized below. Those reported during the blinded placebo-controlled follow-up period are presented in Table 27.

**Table 27. Incidence Rates of at Least 1 Adverse Event of Special Interest From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population**

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 327 | 6.5 (5.8, 7.2) | 25.1 | (22.4, 27.9) | 66 | 1.3 (1.0, 1.7) | 5.8 | (4.5, 7.4) |
| Blood and lymphatic system disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lymphopenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Neutropenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Thrombocytopenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cardiac disorders | 6 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.0) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Acute myocardial infarction | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cardiac failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pericarditis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Tachycardia | 1 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Endocrine disorders | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Hypothyroidism | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Eye disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ocular hyperaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Gastrointestinal disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Ascites | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| General disorders and administration site conditions | 261 | 5.2 (4.6, 5.8) | 20.0 | (17.7, 22.6) | 15 | 0.3 (0.2, 0.5) | 1.3 | (0.7, 2.2) |
| Chest discomfort | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Chest pain | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Injection site bruising | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Pyrexia | 251 | 5.0 (4.4, 5.6) | 19.2 | (16.9, 21.8) | 8 | 0.2 (0.1, 0.3) | 0.7 | (0.3, 1.4) |
| Swelling | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## Table 27. Incidence Rates of at Least 1 Adverse Event of Special Interest From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Immune system disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Allergic oedema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Infections and infestations | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Herpes zoster | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Oral herpes | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Varicella zoster virus infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injury, poisoning and procedural complications | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Bone contusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Contusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Periorbital haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Post procedural haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Investigations | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Antinuclear antibody positive | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hepatic enzyme increased | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Metabolism and nutrition disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Diabetes mellitus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Diabetic ketoacidosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Musculoskeletal and connective tissue disorders | 42 | 0.8 (0.6, 1.1) | 3.2 | (2.3, 4.4) | 18 | 0.4 (0.2, 0.6) | 1.6 | (0.9, 2.5) |
| Arthralgia | 42 | 0.8 (0.6, 1.1) | 3.2 | (2.3, 4.4) | 16 | 0.3 (0.2, 0.5) | 1.4 | (0.8, 2.3) |
| Arthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Psoriatic arthropathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Nervous system disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Bell's palsy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Neuralgic amyotrophy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Seizure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Renal and urinary disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |

## Table 27. Incidence Rates of at Least 1 Adverse Event of Special Interest From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Cystitis haemorrhagic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Haematuria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Reproductive system and breast disorders | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Heavy menstrual bleeding | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Intermenstrual bleeding | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Respiratory, thoracic and mediastinal disorders | 8 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.2) | 10 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.6) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Asthma | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Epistaxis | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pharyngeal swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Respiratory failure | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Sneezing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Throat tightness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Skin and subcutaneous tissue disorders | 11 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.5) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Alopecia areata | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Erythema | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pruritus | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Psoriasis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Rash | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Rash erythematous | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Urticaria | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Vascular disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Deep vein thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Flushing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Haematoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hypotension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

**Table 27. Incidence Rates of at Least 1 Adverse Event of Special Interest From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population**

| | Vaccine Group (as Administered) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | Placebo (N[a]=5020, TE[b]=11.3) | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (09:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_aesi_soc_saf

## Lymphadenopathy

Lymphadenopathy is considered an adverse reaction to the vaccine.

During the blinded placebo-controlled follow-up period, lymphadenopathy was reported in 135 BNT162b2 participants (2.7%) and 4 placebo participants (0.1%) (Table 28; Supplemental Table 14.57). Most cases (134 [2.7%]) in the BNT162b2 group and 1 case in the placebo group were considered by the investigator as related to study intervention (Section 5.2.2.1.1.3). All cases of lymphadenopathy were mild or moderate in severity, and the majority were located in the axilla or cervical nodes. Median onset was 2.0 and 13.0 days after booster vaccination in the BNT162b2 and placebo groups, respectively. The events resolved with median duration of 4.0 and 3.0 days in the BNT162b2 and placebo groups, respectively.

As noted in Section 5.2.2.1.1.2.1, lymphadenopathy frequency among BNT162b2 recipients was higher in younger (16 to 55 years of age) compared with older (>55 years of age) participants (4.0% vs 1.0%), and higher in female participants than in male participants (3.5% vs 1.8%). Other events similar to lymphadenopathy reported in the BNT162b2 group were axillary pain, lymph node pain, and lymphadenitis, reported by ≤1.0% of participants (Supplemental Table 14.57).

During the open-label follow-up period for original placebo participants who then received BNT162b2 after unblinding, lymphadenopathy was reported in 56 participants (1.3%;

Table 29), all events of lymphadenopathy were considered related by the investigator. The frequency of lymphadenopathy after BNT162b2 booster dose administration was 1.8% in the younger group and 0.7% in the older group. All cases of lymphadenopathy were mild or moderate in severity, and the majority were located in the axilla or cervical nodes. Median onset was 2.0 days after booster vaccination. The events resolved with median duration of 4.0 days.

No additional cases of lymphadenopathy were reported during the open-label follow-up period (to the data cutoff date) for original BNT162b2 participants.

**Table 28. Participants Reporting Lymphadenopathy From Booster Vaccination to Unblinding Date – Blinded Follow-Up Period – Safety Population**

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=135) n[b] (%) | Placebo (N[a]=4) n[b] (%) |
| Severity | | |
| Mild | 95 (70.4) | 3 (75.0) |
| Moderate | 40 (29.6) | 1 (25.0) |
| Onset day after Booster vaccination[c] | | |
| n | 135 (100.0) | 4 (100.0) |
| Mean (SD) | 2.1 (0.84) | 24.8 (32.26) |
| Median | 2.0 | 13.0 |
| Min, Max | 1 - 6 | 1 - 72 |
| Duration (Days) | | |
| n | 133 (98.5) | 1 (25.0) |
| Mean (SD) | 5.3 (4.75) | 3.0 (NE) |
| Median | 4.0 | 3.0 |
| Min, Max | 2 - 33 | 3 - 3 |
| Unknown[d] | 2 (1.5) | 3 (75.0) |

Abbreviation: NE = not estimable.
a. N = number of participants reporting lymphadenopathy. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the event. Participants reporting more than 1 occurrence of the event were counted by maximum severity, earliest date of onset, and longest duration.
c. Day 1 is the day of booster vaccination.
d. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 29MAR2022 (16:13)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: /nda2_ubBIA/C4591031_A_SBLA/adae_lymph_saf

**Table 29. Participants Reporting Lymphadenopathy From BNT162b2 Booster Vaccination to the Cutoff Date – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population**

| | Vaccine Group (as Administered) |
|---|---|
| | BNT162b2 (30 µg) (N[a]=56) n[b] (%) |
| Severity | |
| Mild | 41 (73.2) |
| Moderate | 15 (26.8) |
| Onset day after BNT162b2 Booster vaccination[c] | |
| n | 56 (100.0) |
| Mean (SD) | 2.0 (0.56) |
| Median | 2.0 |
| Min, Max | 1 - 4 |
| Duration (Days) | |
| n | 54 (96.4) |
| Mean (SD) | 4.3 (2.79) |
| Median | 4.0 |
| Min, Max | 1 - 20 |
| Unknown[d] | 2 (3.6) |

a. N = number of participants reporting lymphadenopathy. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the event. Participants reporting more than 1 occurrence of the event were counted by maximum severity, earliest date of onset, and longest duration.
c. Day 1 is the day of BNT162b2 booster vaccination.
d. Includes those events where the resolution date is partial or missing.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 29MAR2022 (16:20)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBEA/adae_lymph_ol_saf

## Appendicitis

Cases of appendicitis were examined in the placebo-controlled period of the study (including PTs of appendicitis perforated and complicated appendicitis). There were 2 cases of appendicitis and 2 cases of appendicitis perforated in the BNT162b2 group, and no cases in the placebo group (Supplemental Table 14.57). Both cases of appendicitis and 1 case of appendicitis perforated were reported as SAEs, and all of the cases were considered not related to study intervention (Appendix 16.2.7.4).

During the open-label follow-up period (to the data cutoff date) for original BNT162b2 participants, 1 unrelated SAE of appendicitis was reported with onset at Day 186 post-booster and reported as recovered/resolved within 5 days.

During the open-label follow-up period for original placebo participants who then received BNT162b2 after unblinding, no cases of appendicitis were reported.

Narratives for these events are located in Section 14.

**Bell's Palsy**

In the placebo group, 1 participant experienced moderate right-side Bell's palsy with onset at 15 days after Dose 3 (placebo), reported as recovered/resolved at the time of the data cutoff date. This case was considered as not related to study intervention. This case was previously discussed in Section 5.2.2.5.1 of the 2 month analysis interim CSR (dated 18 November 2021). There were no cases of Bell's palsy reported by participant's in the BNT162b2 group.

**Myocarditis/Pericarditis**

During the blinded follow-up period, 1 participant in the placebo group (older age group [≥55 years]) reported an SAE of pericarditis with onset at 67 days after Dose 3 (placebo), that was reported as recovered/resolved (duration 46 days) at the time of data cutoff date. The case was considered as not related to study intervention.

In addition, 1 participant in the placebo group (40 years of age) experienced an SAE of myocarditis (myopericarditis) during the blinded follow-up period (onset at Day 65) that was reported post unblinding (Section 14). The participant received BNT162b2 off-study on Study Day 65. Twelve hours after the dose, the participant had severe precordial chest pain, tachycardia, and a fever of 39˚C and was admitted to the ICU with suspected MI. A cardiac MRI and a coronary CT showed normal results. The medical evaluation during the hospitalization was carried out by ICU physicians. The participant was discharged from the hospital on Study Day 71 without a completed diagnosies; granted by a cardiologist. The discharge summary stated that the possible diagnosis was myopericarditis (vaccination reaction). The diagnosis of myopericarditis was based on the temporal relationship with the dose of the Pfizer vaccine received off-study and the symptoms reported by the subject during hospitalization. The participant was followed-up and had more tests performed that were normal (ECHO and Holter). The event outcome was recovered/resolved within 7 days and considered as not related to study intervention.

During the open-label follow-up period (to the data cutoff date) for original BNT162b2 participants, no cases of myocarditis or pericarditis were reported.

During the open-label follow-up period for original placebo participants who then received BNT162b2 after unblinding, no cases of myocarditis or pericarditis were reported.

### 5.2.2.5.2. Other Events of Clinical Interest

Additional AEs of clinical interest, including those on the CDC AESI list, were evaluated based on sponsor agent safety data review. These AEs were identified from the C4591031 study database as of the data cutoff date (08 February 2022). From this analysis, notable pertinent negatives (ie, no cases reported in this population as of the data cutoff for this submission) with

regard to the CDC list of AESIs included, but were not limited to, autoimmune or demyelination events, meningitis, encephalitis, optic neuritis, Kawasaki disease, MIS-C, or acute respiratory distress syndrome.

AEs of clinical interest are presented in Table 27 for the blinded placebo-controlled follow-up period, with most SOCs showing no numerical difference between the BNT162b2 and placebo groups. SOCs which did include PTs more frequently reported after BNT162b2 compared to placebo, or otherwise considered of particular clinical interest, are summarized below.

**Blood and Lymphatic Disorders**

There were no numerical differences between BNT162b2 and placebo groups in the blood and lymphatic system disorders SOC (Table 27) during the blinded placebo-controlled follow-up period. There was 1 participant in the BNT162b2 group who had concurrent non-serious events of mild transient lymphopenia and thrombocytopenia (assessed as related). This case was previously discussed in detail in Section 5.2.2.5.2 of the 2 month analysis interim CSR (dated 18 November 2021).

During the open-label follow-up period (to the data cutoff date) for original BNT162b2 participants, 1 case of sickle cell anaemia with crisis (SAE) was reported with onset at Day 64 post-booster. The event was reported as resolved/recovered within 2 days and considered not related to the study intervention. A nonserious case of leukocytosis was reported with onset at Day 96. The event was reported as resolved/recovered within 13 days and considered unrelated to the study intervention.

During the open-label follow-up period for original placebo participants who then received BNT162b2 after unblinding, no cases were reported within the blood and lymphatic disorders (other than lymphadenopathy, discussed in Section 5.2.2.5.1, and lymph node pain in 3 participants [0.1%])).

**Cardiac Disorders**

During the blinded placebo-controlled follow-up period, 3 participants (0.1%) in the BNT162b2 group compared with none in the placebo group reported events of tachycardia (Table 27). These events were previously discussed in Section 5.2.2.5.2 of the 2 month analysis interim CSR (dated 18 November 2021). No additional events of tachycardia were reported during the open-label follow-up period for participants who originally received BNT162b2 or those who originally received placebo and then received BNT162b2 after unblinding.

During the blinded placebo-controlled follow-up period, 5 cases (n=3 in BNT162b2 and n=2 in placebo) were reported of myocardial infarction or acute myocardial infarction, showing no imbalance between groups; all of these events were unrelated except 1 event of acute myocardial infarction in the placebo group considered by the investigator as related to study intervention.

During the open-label follow-up period (to the data cutoff date) for original BNT162b2 participants, 1 case of myocardial infarction with a fatal outcome was reported with onset on Day 147 after booster administration; the event was considered to be unrelated to study intervention by the investigator. This participant also reported an unrelated SAE of hemorrhagic shock 137 days post-booster. A narrative for this event is provided in Section 14. There was one case of acute myocardial infarction with onset at 87 days post-booster, reported as recovered/resolved at the time of the data cutoff date. This case was considered as not related to study intervention

During the open-label follow-up period for original placebo participants who then received BNT162b2 after unblinding, no related cases of cardiac disorders were reported. One case of non-serious palpitation was reported with onset at Day 6 post booster, resolving in 2 days. The event was considered not related to study intervention by the investigator. One case of atrial fibrillation was reported as an SAE (Table 26) with onset at Day 22 post booster, resolving in 15 days. The event was considered not related to study intervention.

**General Disorders and Administration Site Conditions**

During the blinded placebo-controlled follow-up period, there was a numerical difference for events of pyrexia, which was reported by 251 participants (5.0%) in the BNT162b2 group compared with 8 participants (0.2%) in the placebo group; and for events of swelling, which was reported by 4 participants (0.1%) in the BNT162b2 group compared to none in the placebo group (Table 27). These are recognized as reactogenicity events known to be associated with BNT162b2 vaccination. There was no numerical difference between groups in the few events of chest pain or chest discomfort.

During the open-label follow-up period (to the data cutoff date) for original BNT162b2 participants, 1 SAE of chest pain with onset at Day 177 post-booster resolved/recovered within 2 days, and 1 SAE of non-cardiac chest pain with onset at Day 99 and resolved/recovered within a day were reported. Both cases were considered not related to study intervention by the investigator. There were no cases of pyrexia or swelling.

During the open-label follow-up period for original placebo participants who then received BNT162b2 after unblinding, pyrexia and swelling were reported in 133 (3.0%) and 4 (0.1%) participants, respectively. No cases of chest pain or chest discomfort were reported.

**Musculoskeletal and Connective Tissue Disorders**

During the blinded placebo-controlled follow-up period, there was a numerical difference for events of arthralgia, which was reported by 42 participants (0.8%) in the BNT162b2 group compared with 16 participants (0.3%) in the placebo group (Table 27). Most events in the BNT162b2 group occurred within 7 days of booster vaccination and resolved within several days of onset and may therefore represent reactogenicity. One event of psoriatic arthropathy was reported in the placebo group.

During the open-label follow-up period (to the data cutoff date) for original BNT162b2 participants, 1 case of arthralgia was reported.

During the open-label follow-up period for original placebo participants who then received BNT162b2 after unblinding, 14 (0.3%) participants reported arthralgia.

**Skin and Subcutaneous Tissue Disorders**

Rash is considered an adverse reaction to vaccine as noted in the EUA Fact Sheet. During the blinded placebo-controlled follow-up period, there was a numerical difference for events of rash, which was reported by 4 participants (0.1%) in the BNT162b2 group compared with 1 participant (0.0%) in the placebo group (Table 27). In the BNT162b2 group, only 1 of the 4 rashes was considered by the investigator as related to study intervention (moderate rash on the chest and abdomen with onset 2 days post-booster and resolved 15 days after onset). Rashes in the BNT162b2 group typically occurred within 2 to 8 days of booster vaccination; 2 of the 4 resolved 3 days after onset, 1 resolved 15 days after onset, and 1 was ongoing as of the data cutoff date; and anatomical locations included the face, neck, chest and abdomen, or generalized.

There was no imbalance between groups in the few events of pruritis, urticaria, alopecia areata, erythema, psoriasis, and rash erythematous (Table 27).

During the open-label follow-up period (to the data cutoff date) for original BNT162b2 participants, 1 participant reported a nonserious, unrelated event of rash maculo-papular with onset at Day 115 post-booster. The event was reported as recovered/resolved at the time of the data cutoff date.

During the open-label follow-up period for original placebo participants who then received BNT162b2 after unblinding, events of alopecia (n=1, not related), dermatitis atopic (n=1, related), erythema (n=2, both related), pruritus (n=2, both related), rash (n=1, related) and urticaria (n=1, not related) were reported, none of which were serious (Table 26 and Supplemental Table 14.108).

**Nervous System Disorders**

During the blinded placebo-controlled follow-up period, 1 unrelated case of cerebrovascular accident with onset at Day 43 post-booster was reported in the BNT162b2 group. The event was reported as recovered/resolved at the time of the data cutoff date (Table 27). One event of cerebral venous thrombosis was reported in a participant who received a booster dose of placebo. This case was previously discussed in Section 5.2.2.5.2 of the 2 month analysis interim CSR (dated 18 November 2021). One unrelated SAE of cerebrovascular accident with onset at Day 7 and recovered/resolved within 2 days was reported in the placebo group.

During the open-label follow-up period (to the data cutoff date) for original BNT162b2 participants, the following cases were reported:

- 1 unrelated SAE of cerebral haemorrhage with onset at Day 110 post-booster and ongoing at the time of the data cutoff date.
- 1 unrelated SAE of cerebrovascular accident with onset at Day 166 post-booster. The event was reported as recovering/resolving at the time of the data cutoff date.

- 1 non serious unrelated case of intracranial aneurysm with onset at Day 116 post-booster and ongoing at the time of the data cutoff date.

- 1 nonserious case of neuralgic amyotrophy with onset at Day 50 post-booster and reported as recovered/resolved at the time of the data cutoff date (duration 106 days). The event was considered related to study intervention by the investigator.

During the open-label follow-up period for original placebo participants who then received BNT162b2 after unblinding, no cases of cerebral haemorrhage, cerebrovascular accident or intracranial aneurysm were reported.

#### 5.2.2.5.3. Conclusions from Review of Adverse Events of Clinical Interest

Following review of all reported AEs and SAEs for participants ≥16 years of age in Study C4591031, as of the data cutoff date (08 February 2022), there were very few AEs of clinical interest corresponding to those requested by the FDA or per the CDC list of AESIs. Lymphadenopathy and rash have been identified as related to BNT162b2 and are observed after the booster dose. No cases of anaphylaxis or hypersensitivity to vaccine were reported, no serious or severe related rashes were reported after BNT162b2 vaccination, and no cases of myocarditis/pericarditis or Bell's palsy were reported over the course of at least 6 months of follow-up after BNT162b2 vaccination in the study in individuals ≥16 years of age. AEs of clinical interest continue to be monitored in all participants in ongoing Study C4591031 and the BNT162b2 vaccine program.

### 5.2.3. Other Safety Evaluations

#### 5.2.3.1. Severe COVID-19 Illness

Severe cases of COVID-19 following booster vaccination were evaluated in efficacy analyses. During the blinded follow-up period (Section 5.1.1.2), there were 3 cases in the placebo group, which is consistent with prior analyses of efficacy for all Phase 2/3 participants ≥12 years of age in registrational Study C4591001 that have consistently shown confinement of severe cases predominantly to the placebo group. After unblinding, 7 severe cases were reported during the time when the Omicron variant was the predominant strain, with onset occurring ≥166 days post-booster in original BNT162b2 recipients and ≥73 days post-booster in placebo participants who then received BNT162b2 after unbinding (Section 5.1.2.2). Overall, these results suggest no evidence for VAED, including VAERD, and are more than likely secondary to decreased neutralizing antibody titers against the Omicron strain, which has been recently reported in the literature.[15]

#### 5.2.3.2. Pregnancy

Pregnancies were reported as EDPs if occurring in a participant or participant's partner within 28 days after last dose of study intervention. Beyond 28 days after the last dose of study intervention, any pregnancy that occurred was not considered EDP for this study (Appendix 16.1.1, Protocol Section 8.3.5.1).

At the time of the data cutoff date (08 February 2022), EDP occurred within 28 days after last dose of study intervention for 4 participants, including 1 who originally received

BNT162b2 and 3 who originally received placebo (and then received BNT162b2 after unblinding) (Appendix 16.2.7.7). (Pregnancies occurring >28 days after last dose were also reported for 2 participants who originally received BNT162b2.)

Two of these participants had an outcome of spontaneous abortion that was reported as an SAE during the blinded follow-up period (Table 23; Appendix 16.2.7.4): 1 participant in the placebo group (reported in the 2-month analysis interim CSR), and 1 participant in the BNT162b2 group. Narratives were prepared for these 2 participants (provided in Section 14). Additionally, during the blinded follow-up period, 1 participant in the BNT162b2 group (whose pregnancy occurred >28 days after last dose) reported an SAE of spontaneous abortion (Table 23).

## 5.3. Summary of Evaluation of Response to Study Intervention

### 5.3.1. Efficacy

**Relative Vaccine Efficacy from Booster Dose to Data Cutoff Date**

The RVE following booster vaccination was estimated from 7 days post-booster to the data cutoff date (08 February 2022) during the blinded placebo-controlled follow-up period. Notably, the COVID-19 cases in this RVE analyses accrued during a period of September 2021 through February 2022 cutoff date, during a time that the highly transmissible Delta variant (27 September through 19 December 2021) and later the more transmissible Omicron variant (20 December 2021 through the data cutoff date of 08 February 2022) had been the predominant SARS-CoV-2 strains in circulation in the US and globally.

During the blinded follow-up period for time points until 4 months after booster vaccination the observed RVE was consistent with that reported 2-month analysis interim CSR (dated 18 November 2021). Relatively few participants remained in the placebo group for time points ≥4 months after booster vaccination (after the study was unblinded and placebo participants began to receive BNT162b2 [Section 3.1.1]) and there were very few cases in placebo participants, precluding a precise estimation of RVE. In the evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days post-booster (Section 5.1.1.1.1):

- The observed RVE for cases confirmed from ≥7 days to <2 months was 95.6% (2-sided 95% CI: 89.4%, 98.6%), based on 5 cases in the BNT162b2 group and 110 cases in the placebo group.
- The observed RVE for cases confirmed from ≥2 to <4 months was 95.1% (2-sided 95% CI: 80.9%, 99.4%), based on 2 cases in the BNT162b2 group and 35 cases in the placebo group.
- The overall RVE observed was 63.9% (2-sided 95% CI: 51.1%, 73.5%), based on 63 cases in the BNT162b2 group and 148 cases in the placebo group accrued from booster vaccination to the data cutoff of 08 February 2022.

The time frame for the overall RVE includes later time points (up to ≥6 months after booster vaccination) that are confounded by the study unblinding and decreased participant numbers, and also influenced by waning vaccine efficacy over time and the Omicron variant wave. As illustrated in Figure 3 and discussed in Section 5.1.2.1, additional analysis of COVID-19 cases through the entire study follow-up period revealed that during the Omicron variant wave cases increased in both original BNT162b2 recipients ('early' vaccinees) and placebo participants who later crossed over to BNT162b2 ('later' vaccinees) compared to cases during the Delta variant wave. Additionally, during the Omicron variant wave, lower IRs in 'early' vaccinees (with <4 months since booster vaccination) compared to 'later' vaccinees (with ≥5 months since booster vaccination) suggest that vaccine efficacy against Omicron wanes with increasing time since BNT162b2 booster vaccination, consistent with real world efficacy data.[16,17,18]

RVE results were similar in the evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days post-booster (Section 5.1.1.1.2) and the all-available efficacy population (Section 5.1.1.1.3), with observed RVEs ≥94.8% for cases confirmed from ≥7 days to <2 months and from ≥2 to <4 months after booster vaccination and overall RVEs (from booster vaccination to the data cutoff date) of 62.4% and 61.2%, respectively.

Signs and symptoms were associated with 63 and 148 cases in the BNT162b2 and placebo group, respectively, confirmed ≥7 days post-booster in the evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days post-booster. The frequencies of participants with ≥4 reported signs and symptoms were generally higher in the placebo group (range: 10.1-10.8%) than the BNT162b2 group (range: 3.2-9.5%). Across vaccine groups, the most commonly reported were new or increased cough (71.1%) and sore throat (45.0%, including 60.3% in the BNT162b2 group vs 38.5% in the placebo group). Other signs and symptoms were reported in the BNT162b2 group at similar or lower frequencies than the placebo group.

For most subgroups with enough cases and participants for precise RVE analyses, the confirmed COVID-19 cases from 7 days after booster vaccination were similar to the overall RVE in the evaluable efficacy population without evidence of SARS-CoV-2 infection prior to 7 days post-booster (63.9% for cases accrued from booster vaccination to the data cutoff).

During the blinded follow-up period, 3 cases were reported in the all-available efficacy population that met severe criteria per the FDA definition (Section 5.1.1.2), all in the placebo group and in participants who were baseline SARS-CoV-2 negative. No cases were reported per the CDC criteria for severity.

After unblinding, in the all-available efficacy population there were 7 cases meeting severe criteria; all occurred after 20 December 2021, when the Omicron variant was the predominant strain, in participants who were baseline SARS-CoV-2 negative. In original BNT162b2 participants, there were 5 severe cases: 3 met the FDA definition, 1 met the CDC definition, and 1 met both definitions (Section 5.1.2.2). In placebo participants who later received BNT162b2, there were 2 severe cases that met the FDA definition.

These results indicate that a booster dose of BNT162b2 30 µg given ≥6 months after the primary 2-dose series of BNT162b2 30 µg vaccination provided protection against COVID-19 during the Delta variant wave, and sustained up to 4 months after vaccination; longer term protection against Delta variant relative to placebo cannot be estimated from this study due to unblinding and crossover of placebo control participants. For the same reason, RVE of boosted to non-boosted participants during the Omicron variant wave cannot be estimated in this study. Although the IR during Omicron wave is much higher than that of Delta wave, the IR in those participants that were 'later' vaccinated is lower than those participants that were 'early' vaccinated, which implies better protection against Omicron with recent vaccination.

### 5.3.2. Safety

The C4591031 safety endpoints for Substudy A did not include solicited reactogenicity (local reactions, systemic events) of BNT162b2 captured via e-diary. All such events were reported as AEs.

Phase 3 data from over 10,000 participants ≥16 years of age after a booster dose of BNT162b2 30 µg or placebo showed the booster administration was safe and well-tolerated.

Overall, the AE profile after booster vaccination reflected mostly reactogenicity events and did not suggest any new clinically important short-term safety concerns for BNT162b2 booster vaccination. Most AEs were mild or moderate in severity. Subgroup analyses did not suggest any specific safety concerns with regard to age, sex, race, ethnicity, country, baseline SARS-CoV-2 status, or HIV positive status.

Considering AE frequencies by time period:

- For the blinded placebo-controlled follow-up period from booster vaccination to the unblinding date (Section 5.2.2.1.1), a greater proportion of participants in the BNT162b2 group (26.4%) reported any AE compared with the placebo group (7.8%). This was driven primarily by any AEs considered by the investigator as related to study intervention, reported by 23.9% of participants in the BNT162b2 group and 4.2% of participants in the placebo group. Most AEs reported during this period reflect reactogenicity events.

- For the open-label follow-up period of original BNT162b2 recipients (Section 5.2.2.1.2), the frequency of AEs in the BNT162b2 group was 1.6%; this is markedly reduced relative to any AEs reported from booster vaccination to the unblinding date (26.4%).

- For the blinded placebo-controlled and open-label follow-up periods from booster vaccination to 6 months after booster vaccination of original BNT162b2 participants with at least 6-months follow-up (Section 5.2.2.1.3), there were 27.3% of participants with any AEs; those assessed as related were reported in 24.0%.

- For the open-label follow-up period of original placebo recipients who then received BNT162b2 after unblinding (Section 5.2.2.1.4), the AE profile was similar to those who originally received BNT162b2. The proportion of original placebo recipients who then

were unblinded and received BNT162b2 who experienced any AE was 19.3%, which was driven primarily by any AEs considered by the investigator as related to study intervention (17.4%). Most AEs reported during this period reflect reactogenicity events.

After booster vaccination, there were few AEs of clinical interest corresponding to the CDC list of AESIs reported in the booster safety population. Both lymphadenopathy and rash were more frequently reported after a booster dose of BNT162b2 as compared with placebo, and both of these events are known to be adverse reactions of BNT162b2. No cases of vaccine-associated anaphylaxis, hypersensitivity, myocarditis/pericarditis, or Bell's palsy after BNT162b2 vaccination in the study were reported up to the data cutoff date.

Few SAEs were reported overall, and showed no imbalance between the BNT162b2 and placebo groups (0.8% and 0.7%, respectively, during the blinded placebo-controlled follow-up period). As of the cutoff date, there were 6 booster recipients with a subsequently reported AE leading to withdrawal (none assessed as related) and 9 deaths (none assessed as related).

Overall, the safety results following at least 6 months of follow-up post-booster in 5000 participants originally randomized to BNT162b2, comprising the combined blinded and open-label periods, showed no new safety concerns associated with booster dosing and were consistent with the known safety and tolerability profile observed following the primary 2-dose series.

## 6. CONCLUSIONS

The relative efficacy in the boosted group showed that, in participants 16 years of age and older, BNT162b2 at 30 µg given ≥6 months after the primary 2-dose series provided protection against COVID-19, and protection was strongest during the Delta variant wave. This was shown in participants irrespective of evidence of prior infection with SARS-CoV-2 and across various demographic subgroups. Severe cases were rare and only observed in BNT162b2 recipients during the Omicron variant wave.

The tolerability and safety profile of BNT162b2 30 µg in participants ≥16 years of age at up to 6 months after booster vaccination (to the data cutoff date) was acceptable and consistent with results previously reported.

## 7. REFERENCES

1. World Health Organization. WHO Director-General's opening remarks at the media briefing on COVID-19. [Internet]. Available from: https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020. Published: 11 March 2020. Accessed: 01 April 2020.
2. Food and Drug Administration. Comirnaty and Pfizer-BioNTech COVID-19 vaccine. [Internet]. Available from: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccine. Accessed: 28 Mar 2021.

3. Pfizer. Real-world evidence confirms high effectiveness of Pfizer-BioNTech COVID-19 vaccine and profound public health impact of vaccination one year after pandemic declared [press release]. [Internet]. Available from: https://www.pfizer.com/news/press-release/press-release-detail/real-world-evidence-confirms-high-effectiveness-pfizer. Accessed: 28 Mar 2021.
4. McGill COVID19 Vaccine Tracker Team. COVID19 vaccine tracker: Pfizer/BioNTech: BNT162b2. [Internet]. Available from: https://covid19.trackvaccines.org/vaccines/6/. Accessed: 28 Mar 2021.
5. Food and Drug Administration. Comirnaty and Pfizer-BioNTech COVID-19 vaccine. BLA approval letter dated August 23, 2021. [Internet]. Available from: https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine. Accessed: 26 Oct 2021.
6. Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Takes Multiple Actions to Expand Use of Pfizer-BioNTech COVID-19 Vaccine. [Internet]. Available from: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-multiple-actions-expand-use-pfizer-biontech-covid-19-vaccine. Accessed: 29 Mar 2022.
7. Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes Second Booster Dose of Two COVID-19 Vaccines for Older and Immunocompromised Individuals. [Internet]. Available from: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and. Accessed: 29 Mar 2022.
8. Polack FP, Thomas SJ, Kitchin N, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. N Engl J Med. 2020;383(27):2603-15.
9. Pfizer. Pfizer and BioNTech confirm high efficacy and no serious safety concerns through up to six months following second dose in updated topline analysis of landmark COVID-19 vaccine study [press release]. [Internet]. Available from: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-confirm-high-efficacy-and-no-serious. Accessed: 09 Dec 2021.
10. Pfizer. Pfizer and BioNTech announce Phase 3 trial data showing high efficacy of a booster dose of their COVID-19 vaccine [press release]. [Internet]. Available from: https://www.pfizer.com/news/press-release/press-release-detail/pfizer-and-biontech-announce-phase-3-trial-data-showing. Accessed: 09 Dec 2021.
11. Agresti A. Introduction: distributions and inference for categorical data. In: Agresti A, ed. Categorical data analysis. 2nd ed. Hoboken, NJ: John Wiley & Sons; 2002: 1-35.
12. Food and Drug Administration. Development and licensure of vaccines to prevent COVID-19. [Internet]. Available from: https://www.fda.gov/media/139638/download. Accessed: 27 April 2021.
13. Centers for Disease Control and Prevention. People with Certain Medical Conditions. [Internet]. Available from: https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-with-medical-conditions.html. Accessed: 27 April 2021.

14. Centers for Disease Control and Prevention (CDC). COVID Data Tracker: Variant Proportions. [Internet]. Available from: https://covid.cdc.gov/covid-data-tracker/#variant-proportions. Accessed: 25 March 2022.
15. Regev-Yochay G, Gonen T, Gilboa M, et al. Efficacy of a Fourth Dose of Covid-19 mRNA Vaccine against Omicron. N Engl J Med. 2022;10.1056/NEJMc2202543.
16. Ferdinands JM, Rao S, Dixon BE, et al. Waning 2-Dose and 3-Dose Effectiveness of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance - VISION Network, 10 States, August 2021-January 2022. MMWR Morb Mortal Wkly Rep. 2022;71(7):255-63.
17. Thompson MG, Natarajan K, Irving SA, et al. Effectiveness of a Third Dose of mRNA Vaccines Against COVID-19-Associated Emergency Department and Urgent Care Encounters and Hospitalizations Among Adults During Periods of Delta and Omicron Variant Predominance - VISION Network, 10 States, August 2021-January 2022. MMWR Morb Mortal Wkly Rep. 2022;71(4):139-45.
18. COVID-19 Vaccine Weekly Surveillance Report. [Internet]. UK Health Security Agency. 24 March 2022. Available from: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1063023/Vaccine-surveillance-report-week-12.pdf. Accessed: 31 March 2022.

## 14. TABLES AND FIGURES REFERRED TO BUT NOT INCLUDED IN THE TEXT

# SUPPLEMENTAL TABLES

## Conduct of Study

### 14.1. Disposition of All Randomized Participants, by Age Group Age Group: 16-55 Years

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2827) n[b] (%) | Placebo (N[a]=2800) n[b] (%) | Total (N[a]=5627) n[b] (%) |
| Randomized | 2827 (100.0) | 2800 (100.0) | 5627 (100.0) |
| Not vaccinated with booster dose | 4 (0.1) | 3 (0.1) | 7 (0.1) |
| Blinded follow-up period | | | |
| Vaccinated with booster dose | 2823 (99.9) | 2797 (99.9) | 5620 (99.9) |
| Completed the 1-month telephone contact | 2813 (99.5) | 2754 (98.4) | 5567 (98.9) |
| Withdrawn from the study | 23 (0.8) | 49 (1.8) | 72 (1.3) |
| Withdrawn after booster vaccination and before the 1-month telephone contact | 7 (0.2) | 16 (0.6) | 23 (0.4) |
| Withdrawn after the 1-month telephone contact | 16 (0.6) | 33 (1.2) | 49 (0.9) |
| Reason for withdrawal from the study | | | |
| Withdrawal by participant | 5 (0.2) | 28 (1.0) | 33 (0.6) |
| Lost to follow-up | 13 (0.5) | 12 (0.4) | 25 (0.4) |
| Protocol deviation | 0 | 4 (0.1) | 4 (0.1) |
| No longer meets eligibility criteria | 1 (0.0) | 2 (0.1) | 3 (0.1) |
| Death | 0 | 1 (0.0) | 1 (0.0) |
| Physician decision | 1 (0.0) | 0 | 1 (0.0) |
| Other | 3 (0.1) | 2 (0.1) | 5 (0.1) |
| Open-label follow-up period | | | |
| Unblinded after booster vaccination and before or on the same day of the 1-month telephone contact | 3 (0.1) | 27 (1.0) | 30 (0.5) |
| Unblinded after the 1-month telephone contact | 2503 (88.5) | 2684 (95.9) | 5187 (92.2) |
| Originally randomized to BNT162b2 | 2506 (88.6) | | |
| Completed the 1-month telephone contact | 3 (0.1) | | |
| Completed the 6-month visit | 2112 (74.7) | | |
| Withdrawn from the study | 146 (5.2) | | |
| Withdrawn before the 6-month visit | 110 (3.9) | | |
| Withdrawn after the 6-month visit | 36 (1.3) | | |
| Reason for withdrawal from the study | | | |
| Protocol deviation | 14 (0.5) | | |
| Withdrawal by participant | 13 (0.5) | | |
| Lost to follow-up | 8 (0.3) | | |
| No longer meets eligibility criteria | 7 (0.2) | | |

## 14.1. Disposition of All Randomized Participants, by Age Group Age Group: 16-55 Years

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2827) n[b] (%) | Placebo (N[a]=2800) n[b] (%) | Total (N[a]=5627) n[b] (%) |
| Withdrawal by parent/guardian | 2 (0.1) | | |
| Death | 1 (0.0) | | |
| Other | 101 (3.6) | | |
| Originally randomized to placebo | | 2711 (96.8) | |
| Withdrawn from the study after unblinding and before BNT162b2 vaccination | | 174 (6.2) | |
| Vaccinated with the booster dose (BNT162b2 [30 µg])[c] | | 2464 (88.0) | |
| Completed the 1-month telephone contact after BNT162b2 vaccination[c] | | 2428 (86.7) | |
| Withdrawn from the study | | 228 (8.1) | |
| Withdrawn after BNT162b2 vaccination and before the 1-month telephone contact | | 3 (0.1) | |
| Withdrawn after the 1-month telephone contact | | 225 (8.0) | |
| Reason for withdrawal from the study | | | |
| Withdrawal by participant | | 4 (0.1) | |
| Lost to follow-up | | 3 (0.1) | |
| Death | | 1 (0.0) | |
| Protocol deviation | | 1 (0.0) | |
| No longer meets eligibility criteria | | 1 (0.0) | |
| Other | | 218 (7.8) | |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
Note: Blinded follow-up period was censored to the cutoff date or the day before date of unblinding (per protocol) or the day before date of receiving COVID-19 vaccine off study, whichever date was earlier.
a. N = number of randomized participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Include one subject whose vaccine (as administered) could not be determined.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:12) Source Data: adds Table Generation: 14MAR2022 (10:46)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubRIA/C4591031_A_SBLA/adds_s002_age_rand

## 14.2. Disposition of All Randomized Participants, by Age Group Age Group: >55 Years

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2261) n[b] (%) | Placebo (N[a]=2248) n[b] (%) | Total (N[a]=4509) n[b] (%) |
| Randomized | 2261 (100.0) | 2248 (100.0) | 4509 (100.0) |
| Not vaccinated with booster dose | 2 (0.1) | 2 (0.1) | 4 (0.1) |
| Blinded follow-up period | | | |
| Vaccinated with booster dose | 2259 (99.9) | 2246 (99.9) | 4505 (99.9) |
| Completed the 1-month telephone contact | 2254 (99.7) | 2213 (98.4) | 4467 (99.1) |
| Withdrawn from the study | 6 (0.3) | 45 (2.0) | 51 (1.1) |
| Withdrawn after booster vaccination and before the 1-month telephone contact | 1 (0.0) | 10 (0.4) | 11 (0.2) |
| Withdrawn after the 1-month telephone contact | 5 (0.2) | 35 (1.6) | 40 (0.9) |
| Reason for withdrawal from the study | | | |
| Withdrawal by participant | 5 (0.2) | 31 (1.4) | 36 (0.8) |
| Lost to follow-up | 1 (0.0) | 7 (0.3) | 8 (0.2) |
| Adverse event | 0 | 1 (0.0) | 1 (0.0) |
| Death | 0 | 1 (0.0) | 1 (0.0) |
| Protocol deviation | 0 | 1 (0.0) | 1 (0.0) |
| No longer meets eligibility criteria | 0 | 1 (0.0) | 1 (0.0) |
| Other | 0 | 3 (0.1) | 3 (0.1) |
| Open-label follow-up period | | | |
| Unblinded after booster vaccination and before or on the same day of the 1-month telephone contact | 4 (0.2) | 23 (1.0) | 27 (0.6) |
| Unblinded after the 1-month telephone contact | 1995 (88.2) | 2168 (96.4) | 4163 (92.3) |
| Originally randomized to BNT162b2 | 1999 (88.4) | | |
| Completed the 1-month telephone contact | 3 (0.1) | | |
| Completed the 6-month visit | 1880 (83.1) | | |
| Withdrawn from the study | 39 (1.7) | | |
| Withdrawn before the 6-month visit | 32 (1.4) | | |
| Withdrawn after the 6-month visit | 7 (0.3) | | |
| Reason for withdrawal from the study | | | |
| Withdrawal by participant | 17 (0.8) | | |
| Protocol deviation | 13 (0.6) | | |
| No longer meets eligibility criteria | 4 (0.2) | | |
| Death | 2 (0.1) | | |
| Lost to follow-up | 1 (0.0) | | |
| Other | 2 (0.1) | | |
| Originally randomized to placebo | | 2191 (97.5) | |
| Withdrawn from the study after unblinding and before BNT162b2 vaccination | | 160 (7.1) | |
| Vaccinated with the booster dose (BNT162b2 [30 µg])[c] | | 1956 (87.0) | |

## 14.2. Disposition of All Randomized Participants, by Age Group Age Group: >55 Years

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2261) n[b] (%) | Placebo (N[a]=2248) n[b] (%) | Total (N[a]=4509) n[b] (%) |
| Completed the 1-month telephone contact after BNT162b2 vaccination[c] | | 1938 (86.2) | |
| Withdrawn from the study | | 10 (0.4) | |
| Withdrawn after BNT162b2 vaccination and before the 1-month telephone contact | | 4 (0.2) | |
| Withdrawn after the 1-month telephone contact | | 6 (0.3) | |
| Reason for withdrawal from the study | | | |
| Withdrawal by participant | | 4 (0.2) | |
| Death | | 3 (0.1) | |
| Lost to follow-up | | 1 (0.0) | |
| No longer meets eligibility criteria | | 1 (0.0) | |
| Other | | 1 (0.0) | |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
Note: Blinded follow-up period was censored to the cutoff date or the day before date of unblinding (per protocol) or the day before date of receiving COVID-19 vaccine off study, whichever date was earlier.
a. N = number of randomized participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Include one subject whose vaccine (as administered) could not be determined.
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## 14.3. Disposition – Participants Not Known to be HIV-Positive

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5062) n[b] (%) | Placebo (N[a]=5024) n[b] (%) | Total (N[a]=10086) n[b] (%) |
| Randomized | 5062 (100.0) | 5024 (100.0) | 10086 (100.0) |
| Not vaccinated with booster dose | 6 (0.1) | 5 (0.1) | 11 (0.1) |
| Blinded follow-up period | | | |
| Vaccinated with booster dose | 5056 (99.9) | 5019 (99.9) | 10075 (99.9) |
| Completed the 1-month telephone contact | 5041 (99.6) | 4943 (98.4) | 9984 (99.0) |
| Withdrawn from the study | 29 (0.6) | 94 (1.9) | 123 (1.2) |
| Withdrawn after booster vaccination and before the 1-month telephone contact | 8 (0.2) | 26 (0.5) | 34 (0.3) |
| Withdrawn after the 1-month telephone contact | 21 (0.4) | 68 (1.4) | 89 (0.9) |
| Reason for withdrawal from the study | | | |
| Withdrawal by participant | 10 (0.2) | 59 (1.2) | 69 (0.7) |
| Lost to follow-up | 14 (0.3) | 19 (0.4) | 33 (0.3) |
| Protocol deviation | 0 | 5 (0.1) | 5 (0.0) |
| No longer meets eligibility criteria | 1 (0.0) | 3 (0.1) | 4 (0.0) |
| Death | 0 | 2 (0.0) | 2 (0.0) |
| Adverse event | 0 | 1 (0.0) | 1 (0.0) |
| Physician decision | 1 (0.0) | 0 | 1 (0.0) |
| Other | 3 (0.1) | 5 (0.1) | 8 (0.1) |
| Open-label follow-up period | | | |
| Unblinded after booster vaccination and before or on the same day of the 1-month telephone contact | 7 (0.1) | 50 (1.0) | 57 (0.6) |
| Unblinded after the 1-month telephone contact | 4483 (88.6) | 4828 (96.1) | 9311 (92.3) |
| Originally randomized to BNT162b2 | 4490 (88.7) | | |
| Completed the 1-month telephone contact | 6 (0.1) | | |
| Completed the 6-month visit | 3981 (78.6) | | |
| Withdrawn from the study | 181 (3.6) | | |
| Withdrawn before the 6-month visit | 139 (2.7) | | |
| Withdrawn after the 6-month visit | 42 (0.8) | | |
| Reason for withdrawal from the study | | | |
| Withdrawal by participant | 29 (0.6) | | |
| Protocol deviation | 26 (0.5) | | |
| No longer meets eligibility criteria | 10 (0.2) | | |
| Lost to follow-up | 9 (0.2) | | |
| Death | 3 (0.1) | | |
| Withdrawal by parent/guardian | 2 (0.0) | | |
| Other | 102 (2.0) | | |
| Originally randomized to placebo | | 4878 (97.1) | |

## 14.3. Disposition – Participants Not Known to be HIV-Positive

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5062) n[b] (%) | Placebo (N[a]=5024) n[b] (%) | Total (N[a]=10086) n[b] (%) |
| Withdrawn from the study after unblinding and before BNT162b2 vaccination | | 334 (6.6) | |
| Vaccinated with the booster dose (BNT162b2 [30 µg])[c] | | 4397 (87.5) | |
| Completed the 1-month telephone contact after BNT162b2 vaccination[c] | | 4343 (86.4) | |
| Withdrawn from the study | | 238 (4.7) | |
| Withdrawn after BNT162b2 vaccination and before the 1-month telephone contact | | 7 (0.1) | |
| Withdrawn after the 1-month telephone contact | | 231 (4.6) | |
| Reason for withdrawal from the study | | | |
| Withdrawal by participant | | 8 (0.2) | |
| Death | | 4 (0.1) | |
| Lost to follow-up | | 4 (0.1) | |
| No longer meets eligibility criteria | | 2 (0.0) | |
| Protocol deviation | | 1 (0.0) | |
| Other | | 219 (4.4) | |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
Note: Blinded follow-up period was censored to the cutoff date or the day before date of unblinding (per protocol) or the day before date of receiving COVID-19 vaccine off study, whichever date was earlier.
a. N = number of randomized participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Include one subject whose vaccine (as administered) could not be determined.
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## 14.4. Important Protocol Deviations

| Protocol Deviation Category/ Subcategory | Vaccine Group (as Randomized) BNT162b2 (30 µg) (N[a]=5088) n[b] (%) | Placebo (N[a]=5048) n[b] (%) | Total (N[a]=10136) n[b] (%) |
|---|---|---|---|
| Concomitant medications | 54 (1.1) | 299 (5.9) | 353 (3.5) |
| Receipt of any other nonstudy coronavirus vaccine at any time during the study. | 40 (0.8) | 263 (5.2) | 303 (3.0) |
| Receipt of blood/plasma products, immunoglobulins, or monoclonal antibodies, from 60 days, or receipt of any passive antibody therapy specific to COVID-19 within 90 days before enrollment through conclusion of the study. | 3 (0.1) | 14 (0.3) | 17 (0.2) |
| Subject received allowable non-study vaccine within 28 days prior to or 28 days after the administration of IP. | 9 (0.2) | 21 (0.4) | 30 (0.3) |
| Subject received chronic systemic treatment with known immunosuppressant medication, or radiotherapy, within 60 days before enrollment through conclusion of the study. | 2 (0.0) | 2 (0.0) | 4 (0.0) |
| Subject received the season influenza vaccine or the pandemic influenza vaccine within 14 days prior to or 14 days after the administration of IP. | 0 | 1 (0.0) | 1 (0.0) |
| Inclusion/exclusion | 79 (1.6) | 70 (1.4) | 149 (1.5) |
| Subject did not meet inclusion criteria 5 (SSA only) - received 2 prior doses of 30 µg BNT162b2 19-42 days apart, with the second dose being at least 175 days before Visit 1 (Day 1) | 64 (1.3) | 62 (1.2) | 126 (1.2) |
| Subject met exclusion criteria 12 (SSA, SSB and SSC only) - Prior receipt of more than 2 doses of BNT162b2 30 µg. | 1 (0.0) | 1 (0.0) | 2 (0.0) |
| Subject met exclusion criteria 3 - Previous clinical or microbiological diagnosis of COVID-19. | 14 (0.3) | 6 (0.1) | 20 (0.2) |
| Subject met exclusion criteria 7 - Receives treatment with radiotherapy, immunosuppressive therapy including cytotoxic agents, or systemic corticosteroids, or planned receipt through the study. | 0 | 1 (0.0) | 1 (0.0) |
| Investigational product | 1 (0.0) | 1 (0.0) | 2 (0.0) |
| IP administered that was deemed not suitable for use by Almac | 0 | 1 (0.0) | 1 (0.0) |
| Incorrect vaccine allocation/assigned to subject | 1 (0.0) | 0 | 1 (0.0) |

Abbreviation: IP = investigational product.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
Note: A participant with multiple deviations is counted only once in each of the specified categories and subcategories.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: addv Table Generation: 14MAR2022 (21:09)
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## 14.5. Safety Population, by Age Group

| Age Group | | Vaccine Group (as Administered) BNT162b2 (30 µg) n[a] | Placebo n[a] | Total n[a] (%) |
|---|---|---|---|---|
| 16-55 Years | Randomized[b] | | | 5627 |
| | Vaccinated | 2823 | 2797 | 5620 (99.9) |
| | Safety population | 2823 | 2797 | 5620 (99.9) |
| | HIV-positive | 19 | 16 | 35 (0.6) |
| | Excluded from safety population | | | 7 (0.1) |
| | Reason for exclusion | | | |
| | Participant did not receive study intervention | | | 7 (0.1) |
| >55 Years | Randomized[b] | | | 4509 |
| | Vaccinated | 2258 | 2247 | 4505 (99.9) |
| | Safety population | 2258 | 2247 | 4505 (99.9) |
| | HIV-positive | 7 | 8 | 15 (0.3) |
| | Excluded from safety population | | | 4 (0.1) |
| | Reason for exclusion | | | |
| | Participant did not receive study intervention | | | 4 (0.1) |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. n = Number of participants with the specified characteristic, or the total sample.
b. This value is the denominator for the percentage calculations.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 14MAR2022 (22:06)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_s003_pop_age

## 14.6. Participants Excluded From Evaluable Efficacy Population Because of Important Protocol Deviations on or Prior to 7 Days After Booster Vaccination – Blinded Follow-Up Period

| Protocol Deviation Category<br>Subcategory | Vaccine Group (as Randomized)<br>BNT162b2 (30 µg) (N[a]=80)<br>n[b] (%) | <br>Placebo (N[a]=76)<br>n[b] (%) |
|---|---|---|
| Concomitant medications | 0 | 7 (9.2) |
| Receipt of any other nonstudy coronavirus vaccine at any time during the study. | 0 | 7 (9.2) |
| Inclusion/exclusion | 79 (98.8) | 69 (90.8) |
| Subject did not meet inclusion criteria 5 (SSA only) - received 2 prior doses of 30 µg BNT162b2 19-42 days apart, with the second dose being at least 175 days before Visit 1 (Day 1) | 64 (80.0) | 61 (80.3) |
| Subject met exclusion criteria 12 (SSA, SSB and SSC only) - Prior receipt of more than 2 doses of BNT162b2 30 µg. | 1 (1.3) | 1 (1.3) |
| Subject met exclusion criteria 3 - Previous clinical or microbiological diagnosis of COVID-19. | 14 (17.5) | 6 (7.9) |
| Subject met exclusion criteria 7 - Receives treatment with radiotherapy, immunosuppressive therapy including cytotoxic agents, or systemic corticosteroids, or planned receipt through the study. | 0 | 1 (1.3) |
| Investigational product | 1 (1.3) | 0 |
| Incorrect vaccine allocation/assigned to subject | 1 (1.3) | 0 |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants excluded from the evaluable efficacy population because of important protocol deviations in the specified group. This value is used as the denominator for the percentage calculations.
b. n = Number of participants with the specific characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: addv Table Generation: 14MAR2022 (10:08)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_eff_pop_dv

## 14.7. Demographic Characteristics, by Age Group – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2823) n[b] (%) | Placebo (N[a]=2797) n[b] (%) | Total (N[a]=5620) n[b] (%) |
| Sex | | | |
| Male | 1353 (47.9) | 1383 (49.4) | 2736 (48.7) |
| Female | 1470 (52.1) | 1414 (50.6) | 2884 (51.3) |
| Race | | | |
| White | 2063 (73.1) | 2063 (73.8) | 4126 (73.4) |
| Black or African American | 310 (11.0) | 295 (10.5) | 605 (10.8) |
| American Indian or Alaska Native | 57 (2.0) | 59 (2.1) | 116 (2.1) |
| Asian | 210 (7.4) | 204 (7.3) | 414 (7.4) |
| Native Hawaiian or other Pacific Islander | 6 (0.2) | 8 (0.3) | 14 (0.2) |
| Multiracial | 162 (5.7) | 155 (5.5) | 317 (5.6) |
| Not reported | 15 (0.5) | 13 (0.5) | 28 (0.5) |
| Ethnicity | | | |
| Hispanic/Latino | 541 (19.2) | 550 (19.7) | 1091 (19.4) |
| Non-Hispanic/non-Latino | 2275 (80.6) | 2245 (80.3) | 4520 (80.4) |
| Not reported | 7 (0.2) | 2 (0.1) | 9 (0.2) |
| Country | | | |
| Brazil | 458 (16.2) | 460 (16.4) | 918 (16.3) |
| South Africa | 103 (3.6) | 105 (3.8) | 208 (3.7) |
| USA | 2262 (80.1) | 2232 (79.8) | 4494 (80.0) |
| Age at vaccination (years) | | | |
| Mean (SD) | 40.5 (9.95) | 40.4 (9.94) | 40.5 (9.95) |
| Median | 41.0 | 42.0 | 42.0 |
| Min, max | (16, 55) | (16, 55) | (16, 55) |
| Baseline SARS-CoV-2 status | | | |
| Positive[c] | 201 (7.1) | 181 (6.5) | 382 (6.8) |
| Negative[d] | 2620 (92.8) | 2612 (93.4) | 5232 (93.1) |
| Unknown | 2 (0.1) | 4 (0.1) | 6 (0.1) |
| Body mass index (BMI) | | | |
| Underweight (<18.5 kg/m$^2$) | 40 (1.4) | 35 (1.3) | 75 (1.3) |
| Normal weight (≥18.5-24.9 kg/m$^2$) | 840 (29.8) | 861 (30.8) | 1701 (30.3) |
| Overweight (≥25.0-29.9 kg/m$^2$) | 932 (33.0) | 902 (32.2) | 1834 (32.6) |
| Obese (≥30.0 kg/m$^2$) | 1011 (35.8) | 999 (35.7) | 2010 (35.8) |

## 14.7. Demographic Characteristics, by Age Group – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2823) n[b] (%) | Placebo (N[a]=2797) n[b] (%) | Total (N[a]=5620) n[b] (%) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 14MAR2022 (08:59)
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## 14.8. Demographic Characteristics, by Age Group – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2258) n[b] (%) | Placebo (N[a]=2247) n[b] (%) | Total (N[a]=4505) n[b] (%) |
| Sex | | | |
| Male | 1104 (48.9) | 1135 (50.5) | 2239 (49.7) |
| Female | 1154 (51.1) | 1112 (49.5) | 2266 (50.3) |
| Race | | | |
| White | 1934 (85.7) | 1940 (86.3) | 3874 (86.0) |
| Black or African American | 161 (7.1) | 165 (7.3) | 326 (7.2) |
| American Indian or Alaska Native | 29 (1.3) | 32 (1.4) | 61 (1.4) |
| Asian | 78 (3.5) | 65 (2.9) | 143 (3.2) |
| Native Hawaiian or other Pacific Islander | 2 (0.1) | 3 (0.1) | 5 (0.1) |
| Multiracial | 46 (2.0) | 41 (1.8) | 87 (1.9) |
| Not reported | 8 (0.4) | 1 (0.0) | 9 (0.2) |
| Ethnicity | | | |
| Hispanic/Latino | 219 (9.7) | 201 (8.9) | 420 (9.3) |
| Non-Hispanic/non-Latino | 2034 (90.1) | 2040 (90.8) | 4074 (90.4) |
| Not reported | 5 (0.2) | 6 (0.3) | 11 (0.2) |
| Country | | | |
| Brazil | 122 (5.4) | 124 (5.5) | 246 (5.5) |
| South Africa | 31 (1.4) | 29 (1.3) | 60 (1.3) |
| USA | 2105 (93.2) | 2094 (93.2) | 4199 (93.2) |
| Age at vaccination (years) | | | |
| Mean (SD) | 65.8 (6.68) | 65.9 (6.64) | 65.8 (6.66) |
| Median | 65.0 | 65.0 | 65.0 |
| Min, max | (56, 86) | (56, 87) | (56, 87) |
| Baseline SARS-CoV-2 status | | | |
| Positive[c] | 88 (3.9) | 81 (3.6) | 169 (3.8) |
| Negative[d] | 2165 (95.9) | 2163 (96.3) | 4328 (96.1) |
| Unknown | 5 (0.2) | 3 (0.1) | 8 (0.2) |
| Body mass index (BMI) | | | |
| Underweight (<18.5 kg/m$^2$) | 17 (0.8) | 14 (0.6) | 31 (0.7) |
| Normal weight (≥18.5-24.9 kg/m$^2$) | 591 (26.2) | 596 (26.5) | 1187 (26.3) |
| Overweight (≥25.0-29.9 kg/m$^2$) | 837 (37.1) | 826 (36.8) | 1663 (36.9) |
| Obese (≥30.0 kg/m$^2$) | 811 (35.9) | 811 (36.1) | 1622 (36.0) |
| Missing | 2 (0.1) | 0 | 2 (0.0) |

## 14.8. Demographic Characteristics, by Age Group – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | **BNT162b2 (30 µg) ($N^a$=2258) $n^b$ (%)** | **Placebo ($N^a$=2247) $n^b$ (%)** | **Total ($N^a$=4505) $n^b$ (%)** |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 14MAR2022 (08:59)
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## 14.9. Demographic Characteristics – Participants Not Known To Be HIV-Positive – Safety Population

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055) n[b] (%) | Placebo (N[a]=5020) n[b] (%) | Total (N[a]=10075) n[b] (%) |
| Sex | | | |
| Male | 2443 (48.3) | 2500 (49.8) | 4943 (49.1) |
| Female | 2612 (51.7) | 2520 (50.2) | 5132 (50.9) |
| Race | | | |
| White | 3986 (78.9) | 3993 (79.5) | 7979 (79.2) |
| Black or African American | 457 (9.0) | 447 (8.9) | 904 (9.0) |
| American Indian or Alaska Native | 86 (1.7) | 91 (1.8) | 177 (1.8) |
| Asian | 287 (5.7) | 269 (5.4) | 556 (5.5) |
| Native Hawaiian or other Pacific Islander | 8 (0.2) | 11 (0.2) | 19 (0.2) |
| Multiracial | 208 (4.1) | 195 (3.9) | 403 (4.0) |
| Not reported | 23 (0.5) | 14 (0.3) | 37 (0.4) |
| Ethnicity | | | |
| Hispanic/Latino | 757 (15.0) | 749 (14.9) | 1506 (14.9) |
| Non-Hispanic/non-Latino | 4286 (84.8) | 4263 (84.9) | 8549 (84.9) |
| Not reported | 12 (0.2) | 8 (0.2) | 20 (0.2) |
| Country | | | |
| Brazil | 580 (11.5) | 582 (11.6) | 1162 (11.5) |
| South Africa | 123 (2.4) | 128 (2.5) | 251 (2.5) |
| USA | 4352 (86.1) | 4310 (85.9) | 8662 (86.0) |
| Age group (at vaccination) | | | |
| 16-55 Years | 2804 (55.5) | 2781 (55.4) | 5585 (55.4) |
| >55 Years | 2251 (44.5) | 2239 (44.6) | 4490 (44.6) |
| 16-17 Years | 46 (0.9) | 44 (0.9) | 90 (0.9) |
| 18-55 Years | 2758 (54.6) | 2737 (54.5) | 5495 (54.5) |
| 56-64 Years | 1078 (21.3) | 1052 (21.0) | 2130 (21.1) |
| 65+ Years | 1173 (23.2) | 1187 (23.6) | 2360 (23.4) |
| Age at vaccination (years) | | | |
| Mean (SD) | 51.8 (15.27) | 51.7 (15.36) | 51.8 (15.31) |
| Median | 53.0 | 53.0 | 53.0 |
| Min, max | (16, 86) | (16, 87) | (16, 87) |
| Baseline SARS-CoV-2 status | | | |
| Positive[c] | 283 (5.6) | 259 (5.2) | 542 (5.4) |
| Negative[d] | 4765 (94.3) | 4754 (94.7) | 9519 (94.5) |
| Unknown | 7 (0.1) | 7 (0.1) | 14 (0.1) |
| Body mass index (BMI) | | | |
| Underweight (<18.5 kg/m$^2$) | 57 (1.1) | 48 (1.0) | 105 (1.0) |
| Normal weight (≥18.5-24.9 kg/m$^2$) | 1426 (28.2) | 1451 (28.9) | 2877 (28.6) |

## 14.9. Demographic Characteristics – Participants Not Known To Be HIV-Positive – Safety Population

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055) n[b] (%) | Placebo (N[a]=5020) n[b] (%) | Total (N[a]=10075) n[b] (%) |
| Overweight (≥25.0-29.9 kg/m$^2$) | 1762 (34.9) | 1721 (34.3) | 3483 (34.6) |
| Obese (≥30.0 kg/m$^2$) | 1808 (35.8) | 1800 (35.9) | 3608 (35.8) |
| Missing | 2 (0.0) | 0 | 2 (0.0) |

Abbreviations: HIV = human immunodeficiency virus; N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test;
SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 14MAR2022 (08:59)
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## 14.10. Demographic Characteristics – HIV-Positive Participants – Safety Population

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=26) n[b] (%) | Placebo (N[a]=24) n[b] (%) | Total (N[a]=50) n[b] (%) |
| Sex | | | |
| Male | 14 (53.8) | 18 (75.0) | 32 (64.0) |
| Female | 12 (46.2) | 6 (25.0) | 18 (36.0) |
| Race | | | |
| White | 11 (42.3) | 10 (41.7) | 21 (42.0) |
| Black or African American | 14 (53.8) | 13 (54.2) | 27 (54.0) |
| Asian | 1 (3.8) | 0 | 1 (2.0) |
| Multiracial | 0 | 1 (4.2) | 1 (2.0) |
| Ethnicity | | | |
| Hispanic/Latino | 3 (11.5) | 2 (8.3) | 5 (10.0) |
| Non-Hispanic/non-Latino | 23 (88.5) | 22 (91.7) | 45 (90.0) |
| Country | | | |
| Brazil | 0 | 2 (8.3) | 2 (4.0) |
| South Africa | 11 (42.3) | 6 (25.0) | 17 (34.0) |
| USA | 15 (57.7) | 16 (66.7) | 31 (62.0) |
| Age group (at vaccination) | | | |
| 16-55 Years | 19 (73.1) | 16 (66.7) | 35 (70.0) |
| >55 Years | 7 (26.9) | 8 (33.3) | 15 (30.0) |
| Age at vaccination (years) | | | |
| Mean (SD) | 50.5 (9.05) | 51.4 (7.89) | 51.0 (8.44) |
| Median | 50.5 | 51.5 | 51.0 |
| Min, max | (33, 67) | (36, 68) | (33, 68) |
| Baseline SARS-CoV-2 status | | | |
| Positive[c] | 6 (23.1) | 3 (12.5) | 9 (18.0) |
| Negative[d] | 20 (76.9) | 21 (87.5) | 41 (82.0) |
| Body mass index (BMI) | | | |
| Underweight (<18.5 kg/m$^2$) | 0 | 1 (4.2) | 1 (2.0) |
| Normal weight (≥18.5-24.9 kg/m$^2$) | 5 (19.2) | 6 (25.0) | 11 (22.0) |
| Overweight (≥25.0-29.9 kg/m$^2$) | 7 (26.9) | 7 (29.2) | 14 (28.0) |
| Obese (≥30.0 kg/m$^2$) | 14 (53.8) | 10 (41.7) | 24 (48.0) |
| Cluster of differentiation 4 (CD4) count | | | |
| 200-500 cells/mm$^3$ | 2 (7.7) | 4 (16.7) | 6 (12.0) |
| >500 cells/mm$^3$ | 17 (65.4) | 13 (54.2) | 30 (60.0) |
| Missing | 7 (26.9) | 7 (29.2) | 14 (28.0) |
| HIV ribonucleic acid (RNA) | | | |
| <50 copies/mL | 18 (69.2) | 17 (70.8) | 35 (70.0) |
| ≥50 copies/mL | 0 | 1 (4.2) | 1 (2.0) |
| Missing | 8 (30.8) | 6 (25.0) | 14 (28.0) |

## 14.10. Demographic Characteristics – HIV-Positive Participants – Safety Population

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=26) n[b] (%) | Placebo (N[a]=24) n[b] (%) | Total (N[a]=50) n[b] (%) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 14MAR2022 (08:59)
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## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Any medical history | 4603 (90.6) | 4537 (89.9) |
| Blood and lymphatic system disorders | 104 (2.0) | 113 (2.2) |
| Abnormal clotting factor | 1 (0.0) | 0 |
| Anaemia | 62 (1.2) | 67 (1.3) |
| Anaemia macrocytic | 1 (0.0) | 0 |
| Anaemia of pregnancy | 1 (0.0) | 0 |
| Anaemia vitamin B12 deficiency | 1 (0.0) | 0 |
| Antiphospholipid syndrome | 3 (0.1) | 1 (0.0) |
| Coagulopathy | 2 (0.0) | 1 (0.0) |
| Eosinophilia | 0 | 1 (0.0) |
| Immune thrombocytopenia | 3 (0.1) | 0 |
| Iron deficiency anaemia | 10 (0.2) | 17 (0.3) |
| Leukocytosis | 1 (0.0) | 1 (0.0) |
| Leukopenia | 4 (0.1) | 1 (0.0) |
| Lymphadenopathy | 3 (0.1) | 5 (0.1) |
| Lymphoid tissue hyperplasia | 1 (0.0) | 1 (0.0) |
| Macrocytosis | 1 (0.0) | 0 |
| Mast cell activation syndrome | 1 (0.0) | 0 |
| Mastocytosis | 1 (0.0) | 0 |
| Neutropenia | 0 | 2 (0.0) |
| Pancytopenia | 1 (0.0) | 0 |
| Pernicious anaemia | 2 (0.0) | 4 (0.1) |
| Polycythaemia | 2 (0.0) | 1 (0.0) |
| Spherocytic anaemia | 0 | 1 (0.0) |
| Splenic lesion | 0 | 1 (0.0) |
| Splenomegaly | 1 (0.0) | 1 (0.0) |
| Thrombocytopenia | 7 (0.1) | 7 (0.1) |
| Thrombocytosis | 0 | 2 (0.0) |
| Thymic cyst | 0 | 1 (0.0) |
| Cardiac disorders | 370 (7.3) | 352 (7.0) |
| Acute coronary syndrome | 0 | 1 (0.0) |
| Acute myocardial infarction | 10 (0.2) | 4 (0.1) |
| Adams-Stokes syndrome | 1 (0.0) | 0 |
| Angina pectoris | 17 (0.3) | 16 (0.3) |
| Aortic valve disease | 1 (0.0) | 0 |
| Aortic valve incompetence | 5 (0.1) | 2 (0.0) |
| Aortic valve prolapse | 1 (0.0) | 0 |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Aortic valve sclerosis | 0 | 1 (0.0) |
| Aortic valve stenosis | 1 (0.0) | 4 (0.1) |
| Arrhythmia | 15 (0.3) | 21 (0.4) |
| Arteriosclerosis coronary artery | 6 (0.1) | 6 (0.1) |
| Arteriospasm coronary | 1 (0.0) | 1 (0.0) |
| Athletic heart syndrome | 1 (0.0) | 0 |
| Atrial fibrillation | 82 (1.6) | 85 (1.7) |
| Atrial flutter | 5 (0.1) | 8 (0.2) |
| Atrial tachycardia | 0 | 1 (0.0) |
| Atrioventricular block | 1 (0.0) | 2 (0.0) |
| Atrioventricular block complete | 2 (0.0) | 2 (0.0) |
| Atrioventricular block first degree | 1 (0.0) | 1 (0.0) |
| Bradycardia | 11 (0.2) | 11 (0.2) |
| Bundle branch block left | 6 (0.1) | 3 (0.1) |
| Bundle branch block right | 1 (0.0) | 4 (0.1) |
| Cardiac amyloidosis | 1 (0.0) | 0 |
| Cardiac arrest | 1 (0.0) | 0 |
| Cardiac disorder | 3 (0.1) | 4 (0.1) |
| Cardiac failure | 3 (0.1) | 8 (0.2) |
| Cardiac failure acute | 1 (0.0) | 0 |
| Cardiac failure chronic | 2 (0.0) | 0 |
| Cardiac failure congestive | 24 (0.5) | 17 (0.3) |
| Cardiac valve disease | 2 (0.0) | 1 (0.0) |
| Cardiac ventricular thrombosis | 0 | 1 (0.0) |
| Cardiomegaly | 1 (0.0) | 0 |
| Cardiomyopathy | 7 (0.1) | 5 (0.1) |
| Cardiovascular disorder | 2 (0.0) | 1 (0.0) |
| Chronic left ventricular failure | 0 | 1 (0.0) |
| Congestive cardiomyopathy | 0 | 1 (0.0) |
| Coronary artery disease | 84 (1.7) | 74 (1.5) |
| Coronary artery dissection | 1 (0.0) | 0 |
| Coronary artery insufficiency | 1 (0.0) | 2 (0.0) |
| Coronary artery occlusion | 3 (0.1) | 0 |
| Extrasystoles | 2 (0.0) | 0 |
| Heart valve incompetence | 0 | 1 (0.0) |
| Hypertensive heart disease | 0 | 1 (0.0) |
| Ischaemic cardiomyopathy | 1 (0.0) | 1 (0.0) |
| Left ventricular failure | 1 (0.0) | 1 (0.0) |
| Left ventricular hypertrophy | 2 (0.0) | 1 (0.0) |
| Long QT syndrome | 0 | 1 (0.0) |
| Microvascular coronary artery disease | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Mitral valve disease | 5 (0.1) | 1 (0.0) |
| Mitral valve incompetence | 7 (0.1) | 7 (0.1) |
| Mitral valve prolapse | 21 (0.4) | 23 (0.5) |
| Mitral valve stenosis | 1 (0.0) | 0 |
| Myocardial infarction | 40 (0.8) | 48 (1.0) |
| Myocardial ischaemia | 2 (0.0) | 0 |
| Myocarditis | 1 (0.0) | 0 |
| Palpitations | 26 (0.5) | 20 (0.4) |
| Pericardial effusion | 2 (0.0) | 0 |
| Pericarditis | 0 | 2 (0.0) |
| Postural orthostatic tachycardia syndrome | 2 (0.0) | 0 |
| Pulmonary valve incompetence | 0 | 2 (0.0) |
| Rheumatic heart disease | 1 (0.0) | 0 |
| Sinus arrhythmia | 2 (0.0) | 0 |
| Sinus bradycardia | 1 (0.0) | 2 (0.0) |
| Sinus node dysfunction | 2 (0.0) | 1 (0.0) |
| Sinus tachycardia | 1 (0.0) | 1 (0.0) |
| Stress cardiomyopathy | 3 (0.1) | 0 |
| Supraventricular extrasystoles | 2 (0.0) | 6 (0.1) |
| Supraventricular tachycardia | 10 (0.2) | 13 (0.3) |
| Tachyarrhythmia | 0 | 1 (0.0) |
| Tachycardia | 12 (0.2) | 11 (0.2) |
| Tachycardia paroxysmal | 0 | 2 (0.0) |
| Tricuspid valve disease | 1 (0.0) | 0 |
| Tricuspid valve incompetence | 0 | 2 (0.0) |
| Ventricular extrasystoles | 19 (0.4) | 14 (0.3) |
| Ventricular fibrillation | 1 (0.0) | 0 |
| Ventricular hypokinesia | 0 | 1 (0.0) |
| Ventricular tachycardia | 3 (0.1) | 3 (0.1) |
| Wolff-Parkinson-White syndrome | 0 | 2 (0.0) |
| Congenital, familial and genetic disorders | 127 (2.5) | 121 (2.4) |
| Acrocephalosyndactyly | 1 (0.0) | 0 |
| Albinism | 1 (0.0) | 0 |
| Alpha-1 antitrypsin deficiency | 0 | 3 (0.1) |
| Anomalous pulmonary venous connection | 1 (0.0) | 0 |
| Arnold-Chiari malformation | 2 (0.0) | 0 |
| Arterial tortuosity syndrome | 0 | 1 (0.0) |
| Arteriovenous malformation | 0 | 2 (0.0) |
| Asplenia | 1 (0.0) | 0 |
| Asymptomatic gene carrier | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Atrial septal defect | 4 (0.1) | 4 (0.1) |
| BRCA2 gene mutation | 1 (0.0) | 0 |
| Benign familial pemphigus | 1 (0.0) | 0 |
| Bicuspid aortic valve | 3 (0.1) | 3 (0.1) |
| Branchial cyst | 0 | 1 (0.0) |
| Cancer gene carrier | 1 (0.0) | 0 |
| Cataract congenital | 1 (0.0) | 0 |
| Cerebral palsy | 0 | 1 (0.0) |
| Chediak-Higashi syndrome | 1 (0.0) | 0 |
| Cleft palate | 2 (0.0) | 0 |
| Coarctation of the aorta | 0 | 1 (0.0) |
| Congenital anomaly | 1 (0.0) | 1 (0.0) |
| Congenital cystic kidney disease | 2 (0.0) | 1 (0.0) |
| Congenital diaphragmatic hernia | 0 | 1 (0.0) |
| Congenital eye disorder | 1 (0.0) | 0 |
| Congenital flat feet | 2 (0.0) | 0 |
| Congenital heart valve disorder | 1 (0.0) | 0 |
| Congenital hydronephrosis | 1 (0.0) | 0 |
| Congenital jaw malformation | 0 | 1 (0.0) |
| Congenital joint malformation | 0 | 1 (0.0) |
| Congenital multiplex arthrogryposis | 0 | 1 (0.0) |
| Congenital musculoskeletal anomaly | 2 (0.0) | 0 |
| Congenital optic nerve anomaly | 0 | 1 (0.0) |
| Congenital pulmonary valve disorder | 0 | 1 (0.0) |
| Congenital renal disorder | 0 | 1 (0.0) |
| Congenital small intestinal atresia | 1 (0.0) | 0 |
| Congenital spinal cord anomaly | 0 | 1 (0.0) |
| Congenital spinal fusion | 1 (0.0) | 0 |
| Congenital spinal stenosis | 1 (0.0) | 1 (0.0) |
| Congenital vas deferens absence | 1 (0.0) | 0 |
| Corneal dystrophy | 3 (0.1) | 5 (0.1) |
| Craniosynostosis | 1 (0.0) | 0 |
| Cryptorchism | 1 (0.0) | 0 |
| Deafness congenital | 1 (0.0) | 2 (0.0) |
| Dermoid cyst | 1 (0.0) | 2 (0.0) |
| Developmental hip dysplasia | 1 (0.0) | 2 (0.0) |
| Dolichocolon | 1 (0.0) | 0 |
| Duodenal atresia | 1 (0.0) | 0 |
| Ear malformation | 0 | 1 (0.0) |
| Ectrodactyly | 0 | 1 (0.0) |
| Ehlers-Danlos syndrome | 4 (0.1) | 2 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Eyelid ptosis congenital | 0 | 1 (0.0) |
| Factor II mutation | 0 | 2 (0.0) |
| Factor V Leiden carrier | 1 (0.0) | 1 (0.0) |
| Factor V Leiden mutation | 4 (0.1) | 5 (0.1) |
| Factor V deficiency | 0 | 2 (0.0) |
| Factor VIII deficiency | 0 | 1 (0.0) |
| Factor XI deficiency | 1 (0.0) | 0 |
| Factor XIII deficiency | 1 (0.0) | 0 |
| Familial mediterranean fever | 1 (0.0) | 0 |
| Familial polycythaemia | 0 | 1 (0.0) |
| Familial tremor | 1 (0.0) | 1 (0.0) |
| Gene mutation | 1 (0.0) | 0 |
| Gilbert's syndrome | 5 (0.1) | 4 (0.1) |
| Glucose-6-phosphate dehydrogenase deficiency | 1 (0.0) | 2 (0.0) |
| Haemangioma congenital | 0 | 1 (0.0) |
| Heart disease congenital | 1 (0.0) | 1 (0.0) |
| Hereditary haemochromatosis | 2 (0.0) | 0 |
| Hereditary motor and sensory neuropathy | 0 | 1 (0.0) |
| Hereditary spherocytosis | 3 (0.1) | 0 |
| Hydrocele | 3 (0.1) | 6 (0.1) |
| Hypertrophic cardiomyopathy | 1 (0.0) | 2 (0.0) |
| Hypophosphatasia | 0 | 1 (0.0) |
| Hypospadias | 1 (0.0) | 0 |
| Intestinal malrotation | 1 (0.0) | 0 |
| Keratosis follicular | 0 | 1 (0.0) |
| Kidney malformation | 1 (0.0) | 0 |
| Klippel-Feil syndrome | 0 | 1 (0.0) |
| Kyphosis congenital | 0 | 1 (0.0) |
| Malformation venous | 0 | 2 (0.0) |
| Marfan's syndrome | 0 | 1 (0.0) |
| Methylenetetrahydrofolate reductase gene mutation | 0 | 1 (0.0) |
| Naevus flammeus | 0 | 1 (0.0) |
| Neurofibromatosis | 2 (0.0) | 1 (0.0) |
| Non-compaction cardiomyopathy | 0 | 1 (0.0) |
| Osteogenesis imperfecta | 0 | 1 (0.0) |
| Otospondylomegaepiphyseal dysplasia | 1 (0.0) | 0 |
| Pectus excavatum | 0 | 1 (0.0) |
| Pelvic kidney | 1 (0.0) | 0 |
| Phimosis | 1 (0.0) | 1 (0.0) |
| Porphyria | 1 (0.0) | 0 |
| Protein S deficiency | 3 (0.1) | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Pulmonary malformation | 1 (0.0) | 0 |
| Pyloric stenosis | 1 (0.0) | 3 (0.1) |
| Renal aplasia | 0 | 1 (0.0) |
| Renal fusion anomaly | 2 (0.0) | 0 |
| Retinitis pigmentosa | 0 | 1 (0.0) |
| Sickle cell anaemia | 1 (0.0) | 0 |
| Sickle cell trait | 1 (0.0) | 2 (0.0) |
| Spina bifida | 1 (0.0) | 0 |
| Spine malformation | 0 | 2 (0.0) |
| Stargardt's disease | 1 (0.0) | 0 |
| Talipes | 1 (0.0) | 1 (0.0) |
| Thalassaemia | 3 (0.1) | 1 (0.0) |
| Thalassaemia alpha | 1 (0.0) | 0 |
| Thalassaemia beta | 1 (0.0) | 0 |
| Thalassaemia minor | 3 (0.1) | 3 (0.1) |
| Thyroglossal cyst | 0 | 1 (0.0) |
| Tourette's disorder | 1 (0.0) | 1 (0.0) |
| Tracheo-oesophageal fistula | 1 (0.0) | 0 |
| Type II hyperlipidaemia | 1 (0.0) | 0 |
| Type IIa hyperlipidaemia | 1 (0.0) | 3 (0.1) |
| Type V hyperlipidaemia | 17 (0.3) | 13 (0.3) |
| Urethral valves | 1 (0.0) | 0 |
| Venous angioma of brain | 1 (0.0) | 0 |
| Ventricular septal defect | 0 | 1 (0.0) |
| Vitello-intestinal duct remnant | 3 (0.1) | 0 |
| Von Willebrand's disease | 0 | 1 (0.0) |
| Ear and labyrinth disorders | 206 (4.1) | 173 (3.4) |
| Auditory disorder | 0 | 1 (0.0) |
| Aural polyp | 1 (0.0) | 0 |
| Cerumen impaction | 5 (0.1) | 2 (0.0) |
| Conductive deafness | 1 (0.0) | 1 (0.0) |
| Deafness | 22 (0.4) | 30 (0.6) |
| Deafness bilateral | 41 (0.8) | 26 (0.5) |
| Deafness neurosensory | 7 (0.1) | 13 (0.3) |
| Deafness unilateral | 23 (0.5) | 11 (0.2) |
| Ear deformity acquired | 0 | 1 (0.0) |
| Ear disorder | 2 (0.0) | 1 (0.0) |
| Ear pain | 2 (0.0) | 0 |
| Ear pruritus | 1 (0.0) | 0 |
| Eustachian tube dysfunction | 2 (0.0) | 0 |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Excessive cerumen production | 1 (0.0) | 0 |
| Exostosis of external ear canal | 0 | 1 (0.0) |
| Hyperacusis | 0 | 1 (0.0) |
| Hypoacusis | 15 (0.3) | 12 (0.2) |
| Inner ear disorder | 1 (0.0) | 0 |
| Meniere's disease | 15 (0.3) | 10 (0.2) |
| Middle ear effusion | 0 | 1 (0.0) |
| Motion sickness | 2 (0.0) | 4 (0.1) |
| Otosclerosis | 1 (0.0) | 1 (0.0) |
| Presbyacusis | 2 (0.0) | 1 (0.0) |
| Sudden hearing loss | 1 (0.0) | 0 |
| Superior semicircular canal dehiscence | 0 | 1 (0.0) |
| Tinnitus | 39 (0.8) | 42 (0.8) |
| Tympanic membrane perforation | 2 (0.0) | 5 (0.1) |
| Tympanic membrane scarring | 0 | 1 (0.0) |
| Vertigo | 37 (0.7) | 28 (0.6) |
| Vertigo positional | 5 (0.1) | 3 (0.1) |
| Endocrine disorders | 596 (11.7) | 541 (10.7) |
| Adrenal cyst | 0 | 1 (0.0) |
| Androgen deficiency | 1 (0.0) | 3 (0.1) |
| Anovulatory cycle | 0 | 1 (0.0) |
| Autoimmune hypothyroidism | 1 (0.0) | 0 |
| Autoimmune thyroiditis | 22 (0.4) | 10 (0.2) |
| Basedow's disease | 9 (0.2) | 7 (0.1) |
| Empty sella syndrome | 0 | 1 (0.0) |
| Endocrine disorder | 0 | 1 (0.0) |
| Goitre | 20 (0.4) | 19 (0.4) |
| Hyperadrenalism | 1 (0.0) | 0 |
| Hyperaldosteronism | 1 (0.0) | 1 (0.0) |
| Hypergonadism | 0 | 1 (0.0) |
| Hyperparathyroidism | 5 (0.1) | 5 (0.1) |
| Hyperparathyroidism primary | 1 (0.0) | 1 (0.0) |
| Hyperplasia adrenal | 1 (0.0) | 0 |
| Hyperprolactinaemia | 1 (0.0) | 1 (0.0) |
| Hyperthyroidism | 24 (0.5) | 26 (0.5) |
| Hypogonadism | 26 (0.5) | 23 (0.5) |
| Hypogonadism male | 4 (0.1) | 0 |
| Hypoparathyroidism | 1 (0.0) | 1 (0.0) |
| Hypopituitarism | 0 | 1 (0.0) |
| Hypothyroidism | 493 (9.7) | 441 (8.7) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Inappropriate antidiuretic hormone secretion | 1 (0.0) | 0 |
| Oestrogen deficiency | 2 (0.0) | 3 (0.1) |
| Parathyroid disorder | 2 (0.0) | 0 |
| Primary hypogonadism | 0 | 1 (0.0) |
| Secondary hypogonadism | 1 (0.0) | 0 |
| Testicular failure | 2 (0.0) | 2 (0.0) |
| Thyroid atrophy | 0 | 1 (0.0) |
| Thyroid cyst | 4 (0.1) | 8 (0.2) |
| Thyroid disorder | 3 (0.1) | 6 (0.1) |
| Thyroid mass | 20 (0.4) | 19 (0.4) |
| Thyroiditis | 2 (0.0) | 2 (0.0) |
| Eye disorders | 673 (13.2) | 677 (13.4) |
| Age-related macular degeneration | 2 (0.0) | 0 |
| Amaurosis fugax | 0 | 1 (0.0) |
| Amblyopia | 4 (0.1) | 3 (0.1) |
| Angle closure glaucoma | 3 (0.1) | 1 (0.0) |
| Anisometropia | 2 (0.0) | 2 (0.0) |
| Asthenopia | 1 (0.0) | 0 |
| Astigmatism | 19 (0.4) | 25 (0.5) |
| Binocular eye movement disorder | 1 (0.0) | 0 |
| Blepharitis | 3 (0.1) | 2 (0.0) |
| Blepharospasm | 0 | 1 (0.0) |
| Blindness | 3 (0.1) | 0 |
| Blindness unilateral | 5 (0.1) | 4 (0.1) |
| Borderline glaucoma | 4 (0.1) | 0 |
| Cataract | 186 (3.7) | 164 (3.3) |
| Cataract diabetic | 0 | 1 (0.0) |
| Cataract nuclear | 1 (0.0) | 2 (0.0) |
| Chalazion | 2 (0.0) | 0 |
| Chorioretinopathy | 2 (0.0) | 1 (0.0) |
| Conjunctival haemorrhage | 0 | 1 (0.0) |
| Conjunctivitis allergic | 3 (0.1) | 0 |
| Corneal degeneration | 1 (0.0) | 0 |
| Corneal disorder | 1 (0.0) | 0 |
| Corneal irritation | 1 (0.0) | 0 |
| Dermatochalasis | 2 (0.0) | 3 (0.1) |
| Diabetic retinopathy | 3 (0.1) | 2 (0.0) |
| Diplopia | 0 | 1 (0.0) |
| Dry age-related macular degeneration | 2 (0.0) | 1 (0.0) |
| Dry eye | 36 (0.7) | 38 (0.8) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Dyschromatopsia | 1 (0.0) | 0 |
| Entropion | 2 (0.0) | 0 |
| Epiretinal membrane | 0 | 4 (0.1) |
| Exfoliation syndrome | 1 (0.0) | 0 |
| Eye allergy | 1 (0.0) | 0 |
| Eye disorder | 2 (0.0) | 1 (0.0) |
| Eye haemorrhage | 0 | 1 (0.0) |
| Eye inflammation | 1 (0.0) | 0 |
| Eye irritation | 1 (0.0) | 0 |
| Eye movement disorder | 1 (0.0) | 0 |
| Eye pruritus | 2 (0.0) | 0 |
| Eyelid cyst | 0 | 2 (0.0) |
| Eyelid ptosis | 6 (0.1) | 6 (0.1) |
| Glaucoma | 68 (1.3) | 63 (1.2) |
| Holmes-Adie pupil | 1 (0.0) | 0 |
| Hypermetropia | 85 (1.7) | 85 (1.7) |
| Iris disorder | 1 (0.0) | 0 |
| Iritis | 3 (0.1) | 2 (0.0) |
| Keratitis | 0 | 1 (0.0) |
| Keratoconus | 1 (0.0) | 4 (0.1) |
| Lenticular opacities | 0 | 1 (0.0) |
| Macular degeneration | 14 (0.3) | 19 (0.4) |
| Macular oedema | 2 (0.0) | 0 |
| Macular scar | 1 (0.0) | 0 |
| Macular telangiectasia | 1 (0.0) | 0 |
| Maculopathy | 2 (0.0) | 0 |
| Meibomian gland dysfunction | 1 (0.0) | 1 (0.0) |
| Mydriasis | 0 | 2 (0.0) |
| Myopia | 238 (4.7) | 222 (4.4) |
| Myopic chorioretinal degeneration | 1 (0.0) | 1 (0.0) |
| Necrotising retinitis | 0 | 1 (0.0) |
| Neovascular age-related macular degeneration | 1 (0.0) | 0 |
| Normal tension glaucoma | 0 | 1 (0.0) |
| Ocular hypertension | 1 (0.0) | 0 |
| Ocular ischaemic syndrome | 1 (0.0) | 0 |
| Ocular rosacea | 1 (0.0) | 1 (0.0) |
| Ocular vascular disorder | 1 (0.0) | 0 |
| Open angle glaucoma | 3 (0.1) | 2 (0.0) |
| Ophthalmoplegia | 1 (0.0) | 0 |
| Optic atrophy | 0 | 1 (0.0) |
| Optic disc drusen | 1 (0.0) | 0 |

## 14.11. Medical History – Safety Population

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|---|---|---|
| Optic ischaemic neuropathy | 0 | 1 (0.0) |
| Papilloedema | 1 (0.0) | 0 |
| Pigment dispersion syndrome | 0 | 1 (0.0) |
| Presbyopia | 71 (1.4) | 100 (2.0) |
| Pterygium | 4 (0.1) | 2 (0.0) |
| Punctate keratitis | 0 | 2 (0.0) |
| Refractive amblyopia | 1 (0.0) | 0 |
| Retinal artery occlusion | 1 (0.0) | 1 (0.0) |
| Retinal degeneration | 0 | 3 (0.1) |
| Retinal detachment | 12 (0.2) | 11 (0.2) |
| Retinal disorder | 0 | 1 (0.0) |
| Retinal haemorrhage | 1 (0.0) | 0 |
| Retinal scar | 3 (0.1) | 1 (0.0) |
| Retinal tear | 5 (0.1) | 1 (0.0) |
| Retinal vascular disorder | 1 (0.0) | 0 |
| Retinal vein occlusion | 0 | 2 (0.0) |
| Retinopathy | 1 (0.0) | 2 (0.0) |
| Retinopathy proliferative | 1 (0.0) | 0 |
| Strabismus | 9 (0.2) | 8 (0.2) |
| Subretinal fluid | 1 (0.0) | 0 |
| Superior limbic keratoconjunctivitis | 1 (0.0) | 0 |
| Uveitis | 0 | 2 (0.0) |
| Vision blurred | 0 | 1 (0.0) |
| Visual acuity reduced | 50 (1.0) | 48 (1.0) |
| Visual impairment | 14 (0.3) | 11 (0.2) |
| Vitreous degeneration | 0 | 1 (0.0) |
| Vitreous detachment | 6 (0.1) | 5 (0.1) |
| Vitreous floaters | 0 | 1 (0.0) |
| Vitreous haemorrhage | 1 (0.0) | 0 |
| Gastrointestinal disorders | 1179 (23.2) | 1145 (22.7) |
| Abdominal discomfort | 1 (0.0) | 0 |
| Abdominal distension | 2 (0.0) | 2 (0.0) |
| Abdominal hernia | 20 (0.4) | 26 (0.5) |
| Abdominal pain | 7 (0.1) | 10 (0.2) |
| Abdominal pain lower | 2 (0.0) | 0 |
| Abdominal pain upper | 4 (0.1) | 2 (0.0) |
| Acquired oesophageal web | 0 | 1 (0.0) |
| Anal fissure | 2 (0.0) | 1 (0.0) |
| Angular cheilitis | 0 | 1 (0.0) |
| Anogenital dysplasia | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Aphthous ulcer | 2 (0.0) | 1 (0.0) |
| Appendix disorder | 1 (0.0) | 0 |
| Barrett's oesophagus | 16 (0.3) | 9 (0.2) |
| Chronic gastritis | 2 (0.0) | 2 (0.0) |
| Coeliac disease | 9 (0.2) | 9 (0.2) |
| Colitis | 6 (0.1) | 2 (0.0) |
| Colitis ischaemic | 0 | 1 (0.0) |
| Colitis microscopic | 1 (0.0) | 3 (0.1) |
| Colitis ulcerative | 6 (0.1) | 5 (0.1) |
| Constipation | 85 (1.7) | 65 (1.3) |
| Crohn's disease | 2 (0.0) | 4 (0.1) |
| Defaecation disorder | 0 | 1 (0.0) |
| Dental caries | 5 (0.1) | 7 (0.1) |
| Diaphragmatic hernia | 1 (0.0) | 1 (0.0) |
| Diarrhoea | 26 (0.5) | 15 (0.3) |
| Diverticulum | 40 (0.8) | 42 (0.8) |
| Diverticulum intestinal | 6 (0.1) | 7 (0.1) |
| Dry mouth | 2 (0.0) | 2 (0.0) |
| Duodenal ulcer | 2 (0.0) | 1 (0.0) |
| Duodenogastric reflux | 1 (0.0) | 0 |
| Dyspepsia | 113 (2.2) | 103 (2.0) |
| Dysphagia | 4 (0.1) | 1 (0.0) |
| Enteritis | 0 | 1 (0.0) |
| Enterovesical fistula | 1 (0.0) | 1 (0.0) |
| Eosinophilic oesophagitis | 6 (0.1) | 1 (0.0) |
| Epigastric discomfort | 0 | 1 (0.0) |
| Femoral hernia | 1 (0.0) | 1 (0.0) |
| Flatulence | 1 (0.0) | 0 |
| Food poisoning | 1 (0.0) | 0 |
| Functional gastrointestinal disorder | 1 (0.0) | 0 |
| Gastric disorder | 2 (0.0) | 1 (0.0) |
| Gastric mucosal lesion | 1 (0.0) | 0 |
| Gastric ulcer | 8 (0.2) | 18 (0.4) |
| Gastric ulcer haemorrhage | 2 (0.0) | 1 (0.0) |
| Gastric ulcer perforation | 1 (0.0) | 0 |
| Gastritis | 23 (0.5) | 18 (0.4) |
| Gastritis erosive | 1 (0.0) | 1 (0.0) |
| Gastrointestinal disorder | 1 (0.0) | 5 (0.1) |
| Gastrointestinal haemorrhage | 2 (0.0) | 2 (0.0) |
| Gastrointestinal pain | 1 (0.0) | 1 (0.0) |
| Gastrointestinal perforation | 0 | 2 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Gastrointestinal polyp | 1 (0.0) | 0 |
| Gastrointestinal ulcer | 0 | 1 (0.0) |
| Gastrooesophageal reflux disease | 622 (12.2) | 615 (12.2) |
| Gingival disorder | 1 (0.0) | 0 |
| Gingival pain | 0 | 1 (0.0) |
| Haematochezia | 1 (0.0) | 0 |
| Haemorrhoids | 61 (1.2) | 48 (1.0) |
| Hiatus hernia | 34 (0.7) | 29 (0.6) |
| Impaired gastric emptying | 3 (0.1) | 2 (0.0) |
| Inflammatory bowel disease | 2 (0.0) | 0 |
| Inguinal hernia | 104 (2.0) | 94 (1.9) |
| Intestinal cyst | 0 | 1 (0.0) |
| Intestinal metaplasia | 1 (0.0) | 0 |
| Intestinal obstruction | 6 (0.1) | 5 (0.1) |
| Intestinal perforation | 2 (0.0) | 0 |
| Intestinal polyp | 0 | 2 (0.0) |
| Intestinal pseudo-obstruction | 1 (0.0) | 0 |
| Intussusception | 0 | 1 (0.0) |
| Irritable bowel syndrome | 89 (1.8) | 85 (1.7) |
| Large intestinal obstruction | 0 | 1 (0.0) |
| Large intestinal ulcer | 1 (0.0) | 0 |
| Large intestine perforation | 4 (0.1) | 0 |
| Large intestine polyp | 50 (1.0) | 40 (0.8) |
| Lip swelling | 0 | 1 (0.0) |
| Lumbar hernia | 3 (0.1) | 0 |
| Malabsorption | 1 (0.0) | 1 (0.0) |
| Malocclusion | 1 (0.0) | 2 (0.0) |
| Mouth cyst | 1 (0.0) | 0 |
| Mouth ulceration | 3 (0.1) | 1 (0.0) |
| Nausea | 15 (0.3) | 8 (0.2) |
| Noninfective sialoadenitis | 1 (0.0) | 0 |
| Odynophagia | 0 | 1 (0.0) |
| Oesophageal achalasia | 1 (0.0) | 0 |
| Oesophageal dilatation | 1 (0.0) | 0 |
| Oesophageal fistula | 1 (0.0) | 0 |
| Oesophageal haemorrhage | 0 | 1 (0.0) |
| Oesophageal perforation | 1 (0.0) | 0 |
| Oesophageal spasm | 0 | 1 (0.0) |
| Oesophageal stenosis | 3 (0.1) | 1 (0.0) |
| Oesophageal ulcer | 1 (0.0) | 1 (0.0) |
| Oesophagitis | 3 (0.1) | 3 (0.1) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Omental infarction | 1 (0.0) | 0 |
| Oral disorder | 1 (0.0) | 0 |
| Oral lichen planus | 0 | 1 (0.0) |
| Pancreatic calcification | 1 (0.0) | 0 |
| Pancreatic cyst | 2 (0.0) | 2 (0.0) |
| Pancreatic failure | 0 | 1 (0.0) |
| Pancreatic pseudocyst | 1 (0.0) | 0 |
| Pancreatitis | 13 (0.3) | 6 (0.1) |
| Pancreatitis acute | 1 (0.0) | 2 (0.0) |
| Pancreatitis chronic | 3 (0.1) | 2 (0.0) |
| Pancreatitis relapsing | 1 (0.0) | 0 |
| Pelvic floor dysfunction | 0 | 1 (0.0) |
| Peptic ulcer | 5 (0.1) | 5 (0.1) |
| Periodontal disease | 1 (0.0) | 0 |
| Pharyngo-oesophageal diverticulum | 0 | 1 (0.0) |
| Proctitis | 0 | 1 (0.0) |
| Proctitis ulcerative | 3 (0.1) | 0 |
| Rectal fissure | 3 (0.1) | 1 (0.0) |
| Rectal haemorrhage | 2 (0.0) | 4 (0.1) |
| Rectal polyp | 0 | 2 (0.0) |
| Rectal prolapse | 1 (0.0) | 2 (0.0) |
| Salivary gland cyst | 2 (0.0) | 0 |
| Salivary gland enlargement | 1 (0.0) | 0 |
| Short-bowel syndrome | 0 | 1 (0.0) |
| Small intestinal obstruction | 2 (0.0) | 3 (0.1) |
| Small intestinal stenosis | 1 (0.0) | 0 |
| Small intestine ulcer | 0 | 1 (0.0) |
| Splenic artery aneurysm | 0 | 1 (0.0) |
| Steatorrhoea | 0 | 1 (0.0) |
| Swollen tongue | 1 (0.0) | 1 (0.0) |
| Tooth disorder | 0 | 1 (0.0) |
| Tooth impacted | 16 (0.3) | 13 (0.3) |
| Tooth loss | 0 | 1 (0.0) |
| Toothache | 1 (0.0) | 4 (0.1) |
| Umbilical hernia | 50 (1.0) | 35 (0.7) |
| Uvulitis | 1 (0.0) | 0 |
| Volvulus | 0 | 2 (0.0) |
| Vomiting | 1 (0.0) | 1 (0.0) |
| General disorders and administration site conditions | 181 (3.6) | 184 (3.6) |
| Adverse drug reaction | 7 (0.1) | 6 (0.1) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Asthenia | 0 | 1 (0.0) |
| Calcinosis | 0 | 1 (0.0) |
| Chest discomfort | 0 | 1 (0.0) |
| Chest pain | 9 (0.2) | 11 (0.2) |
| Chills | 9 (0.2) | 6 (0.1) |
| Chronic fatigue syndrome | 1 (0.0) | 1 (0.0) |
| Cyst | 5 (0.1) | 7 (0.1) |
| Device intolerance | 0 | 1 (0.0) |
| Drug intolerance | 18 (0.4) | 17 (0.3) |
| Dysplasia | 0 | 1 (0.0) |
| Face oedema | 0 | 2 (0.0) |
| Fatigue | 17 (0.3) | 15 (0.3) |
| Feeling abnormal | 1 (0.0) | 0 |
| Gait disturbance | 1 (0.0) | 4 (0.1) |
| Hernia | 12 (0.2) | 19 (0.4) |
| Hyperplasia | 1 (0.0) | 1 (0.0) |
| Hyperthermia malignant | 0 | 1 (0.0) |
| Inflammation | 1 (0.0) | 0 |
| Influenza like illness | 1 (0.0) | 1 (0.0) |
| Infusion site reaction | 1 (0.0) | 0 |
| Injection site bruising | 1 (0.0) | 0 |
| Injection site erythema | 1 (0.0) | 1 (0.0) |
| Injection site pain | 3 (0.1) | 3 (0.1) |
| Injection site swelling | 1 (0.0) | 1 (0.0) |
| Injury associated with device | 1 (0.0) | 0 |
| Localised oedema | 1 (0.0) | 0 |
| Malaise | 0 | 1 (0.0) |
| Nodule | 1 (0.0) | 0 |
| Oedema | 6 (0.1) | 6 (0.1) |
| Oedema peripheral | 48 (0.9) | 37 (0.7) |
| Pain | 28 (0.6) | 28 (0.6) |
| Pelvic mass | 0 | 1 (0.0) |
| Peripheral swelling | 3 (0.1) | 8 (0.2) |
| Precancerous condition | 1 (0.0) | 3 (0.1) |
| Pyrexia | 7 (0.1) | 6 (0.1) |
| Stenosis | 1 (0.0) | 0 |
| Temperature intolerance | 0 | 1 (0.0) |
| Therapy responder | 1 (0.0) | 0 |
| Treatment noncompliance | 1 (0.0) | 0 |
| Ulcer | 2 (0.0) | 1 (0.0) |
| Ulcer haemorrhage | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Vaccination site erythema | 1 (0.0) | 0 |
| Vaccination site pain | 10 (0.2) | 12 (0.2) |
| Vaccination site pruritus | 0 | 1 (0.0) |
| Vaccination site reaction | 1 (0.0) | 0 |
| Xerosis | 2 (0.0) | 0 |
| Hepatobiliary disorders | 274 (5.4) | 241 (4.8) |
| Alcoholic liver disease | 0 | 1 (0.0) |
| Bile duct stone | 1 (0.0) | 2 (0.0) |
| Biliary colic | 2 (0.0) | 1 (0.0) |
| Biliary dyskinesia | 1 (0.0) | 2 (0.0) |
| Biliary obstruction | 0 | 1 (0.0) |
| Biliary tract disorder | 1 (0.0) | 1 (0.0) |
| Cholangitis sclerosing | 1 (0.0) | 0 |
| Cholecystitis | 52 (1.0) | 43 (0.9) |
| Cholecystitis acute | 2 (0.0) | 1 (0.0) |
| Cholelithiasis | 148 (2.9) | 132 (2.6) |
| Cholestasis | 1 (0.0) | 1 (0.0) |
| Cirrhosis alcoholic | 0 | 1 (0.0) |
| Drug-induced liver injury | 1 (0.0) | 0 |
| Gallbladder disorder | 26 (0.5) | 22 (0.4) |
| Gallbladder hypofunction | 1 (0.0) | 2 (0.0) |
| Gallbladder obstruction | 0 | 1 (0.0) |
| Gallbladder oedema | 0 | 1 (0.0) |
| Gallbladder polyp | 2 (0.0) | 2 (0.0) |
| Gallbladder rupture | 0 | 1 (0.0) |
| Hepatic cirrhosis | 3 (0.1) | 2 (0.0) |
| Hepatic cyst | 3 (0.1) | 0 |
| Hepatic lesion | 0 | 1 (0.0) |
| Hepatic mass | 1 (0.0) | 0 |
| Hepatic steatosis | 35 (0.7) | 25 (0.5) |
| Hepatomegaly | 2 (0.0) | 2 (0.0) |
| Immune-mediated hepatitis | 0 | 1 (0.0) |
| Liver disorder | 2 (0.0) | 1 (0.0) |
| Non-alcoholic steatohepatitis | 2 (0.0) | 2 (0.0) |
| Nonalcoholic fatty liver disease | 4 (0.1) | 2 (0.0) |
| Steatohepatitis | 1 (0.0) | 0 |
| Immune system disorders | 1816 (35.7) | 1816 (36.0) |
| Allergic oedema | 2 (0.0) | 1 (0.0) |
| Allergy to animal | 40 (0.8) | 37 (0.7) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Allergy to arthropod bite | 3 (0.1) | 2 (0.0) |
| Allergy to arthropod sting | 27 (0.5) | 26 (0.5) |
| Allergy to chemicals | 8 (0.2) | 2 (0.0) |
| Allergy to fermented products | 1 (0.0) | 0 |
| Allergy to metals | 3 (0.1) | 4 (0.1) |
| Allergy to plants | 8 (0.2) | 12 (0.2) |
| Allergy to surgical sutures | 1 (0.0) | 1 (0.0) |
| Allergy to vaccine | 3 (0.1) | 3 (0.1) |
| Anaphylactic reaction | 3 (0.1) | 1 (0.0) |
| Anti-neutrophil cytoplasmic antibody positive vasculitis | 1 (0.0) | 0 |
| Contrast media allergy | 12 (0.2) | 8 (0.2) |
| Contrast media reaction | 0 | 1 (0.0) |
| Device allergy | 1 (0.0) | 0 |
| Drug hypersensitivity | 826 (16.3) | 871 (17.3) |
| Dust allergy | 13 (0.3) | 13 (0.3) |
| Food allergy | 115 (2.3) | 125 (2.5) |
| Hypersensitivity | 72 (1.4) | 70 (1.4) |
| Iodine allergy | 10 (0.2) | 20 (0.4) |
| Milk allergy | 6 (0.1) | 5 (0.1) |
| Mite allergy | 2 (0.0) | 8 (0.2) |
| Multiple allergies | 2 (0.0) | 10 (0.2) |
| Mycotic allergy | 14 (0.3) | 14 (0.3) |
| Nutritional supplement allergy | 0 | 1 (0.0) |
| Oral allergy syndrome | 0 | 1 (0.0) |
| Perennial allergy | 12 (0.2) | 14 (0.3) |
| Perfume sensitivity | 1 (0.0) | 1 (0.0) |
| Reaction to colouring | 0 | 2 (0.0) |
| Reaction to food additive | 2 (0.0) | 3 (0.1) |
| Reaction to preservatives | 1 (0.0) | 1 (0.0) |
| Rubber sensitivity | 35 (0.7) | 37 (0.7) |
| Sarcoidosis | 4 (0.1) | 3 (0.1) |
| Seasonal allergy | 1033 (20.3) | 1045 (20.7) |
| Serum sickness | 1 (0.0) | 0 |
| Smoke sensitivity | 1 (0.0) | 2 (0.0) |
| Infections and infestations | 814 (16.0) | 773 (15.3) |
| Abscess limb | 1 (0.0) | 1 (0.0) |
| Abscess neck | 0 | 2 (0.0) |
| Acute pulmonary histoplasmosis | 0 | 1 (0.0) |
| Acute sinusitis | 2 (0.0) | 2 (0.0) |
| Adenoiditis | 6 (0.1) | 7 (0.1) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Anal abscess | 1 (0.0) | 0 |
| Anorectal human papilloma virus infection | 0 | 1 (0.0) |
| Appendicitis | 155 (3.1) | 144 (2.9) |
| Appendicitis perforated | 3 (0.1) | 4 (0.1) |
| Arthritis bacterial | 3 (0.1) | 0 |
| Arthritis infective | 1 (0.0) | 0 |
| Aspergillus infection | 1 (0.0) | 0 |
| Bacterial allergy | 0 | 1 (0.0) |
| Bacterial infection | 2 (0.0) | 0 |
| Bacterial toxaemia | 1 (0.0) | 0 |
| Bacterial vaginosis | 0 | 1 (0.0) |
| Bacterial vulvovaginitis | 0 | 1 (0.0) |
| Body tinea | 0 | 1 (0.0) |
| Bronchitis | 8 (0.2) | 11 (0.2) |
| COVID-19 | 14 (0.3) | 5 (0.1) |
| Candida infection | 1 (0.0) | 1 (0.0) |
| Carbuncle | 0 | 1 (0.0) |
| Cellulitis | 4 (0.1) | 6 (0.1) |
| Cervicitis human papilloma virus | 3 (0.1) | 0 |
| Chikungunya virus infection | 2 (0.0) | 3 (0.1) |
| Chlamydial infection | 8 (0.2) | 4 (0.1) |
| Cholecystitis infective | 0 | 1 (0.0) |
| Chronic sinusitis | 21 (0.4) | 26 (0.5) |
| Chronic tonsillitis | 1 (0.0) | 9 (0.2) |
| Clostridium difficile colitis | 0 | 2 (0.0) |
| Clostridium difficile infection | 7 (0.1) | 7 (0.1) |
| Coccidioidomycosis | 1 (0.0) | 0 |
| Conjunctivitis | 0 | 3 (0.1) |
| Conjunctivitis viral | 0 | 1 (0.0) |
| Cyclosporidium infection | 1 (0.0) | 0 |
| Cystitis | 2 (0.0) | 3 (0.1) |
| Cytomegalovirus infection | 0 | 1 (0.0) |
| Dengue fever | 1 (0.0) | 2 (0.0) |
| Device related infection | 0 | 1 (0.0) |
| Diverticulitis | 33 (0.6) | 25 (0.5) |
| Ear infection | 13 (0.3) | 13 (0.3) |
| Eczema infected | 0 | 1 (0.0) |
| Empyema | 0 | 2 (0.0) |
| Encephalitis | 1 (0.0) | 2 (0.0) |
| Encephalomyelitis | 0 | 1 (0.0) |
| Enterobiasis | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Epididymitis | 2 (0.0) | 1 (0.0) |
| Escherichia infection | 2 (0.0) | 1 (0.0) |
| Eyelid infection | 1 (0.0) | 0 |
| Folliculitis | 0 | 5 (0.1) |
| Fracture infection | 0 | 1 (0.0) |
| Fungal infection | 3 (0.1) | 5 (0.1) |
| Fungal skin infection | 5 (0.1) | 2 (0.0) |
| Furuncle | 0 | 1 (0.0) |
| Gastroenteritis | 3 (0.1) | 2 (0.0) |
| Gastroenteritis salmonella | 1 (0.0) | 0 |
| Gastrointestinal bacterial overgrowth | 1 (0.0) | 2 (0.0) |
| Genital herpes | 17 (0.3) | 12 (0.2) |
| Genital herpes simplex | 5 (0.1) | 5 (0.1) |
| Gingivitis | 1 (0.0) | 0 |
| Gonorrhoea | 1 (0.0) | 0 |
| Groin abscess | 1 (0.0) | 0 |
| Groin infection | 1 (0.0) | 0 |
| HIV infection | 8 (0.2) | 5 (0.1) |
| Helicobacter gastritis | 1 (0.0) | 3 (0.1) |
| Helicobacter infection | 4 (0.1) | 0 |
| Hepatitis A | 14 (0.3) | 9 (0.2) |
| Hepatitis B | 1 (0.0) | 4 (0.1) |
| Hepatitis C | 9 (0.2) | 6 (0.1) |
| Hepatitis infectious mononucleosis | 1 (0.0) | 0 |
| Herpes ophthalmic | 2 (0.0) | 0 |
| Herpes simplex | 63 (1.2) | 57 (1.1) |
| Herpes simplex meningitis | 1 (0.0) | 0 |
| Herpes virus infection | 3 (0.1) | 2 (0.0) |
| Herpes zoster | 37 (0.7) | 33 (0.7) |
| Herpes zoster oticus | 1 (0.0) | 0 |
| Histoplasmosis | 5 (0.1) | 1 (0.0) |
| Hordeolum | 1 (0.0) | 0 |
| Human anaplasmosis | 1 (0.0) | 0 |
| Impetigo | 1 (0.0) | 0 |
| Infected cyst | 0 | 1 (0.0) |
| Infection | 0 | 2 (0.0) |
| Infectious mononucleosis | 5 (0.1) | 1 (0.0) |
| Infective tenosynovitis | 0 | 1 (0.0) |
| Influenza | 1 (0.0) | 1 (0.0) |
| Kidney infection | 2 (0.0) | 3 (0.1) |
| Labyrinthitis | 4 (0.1) | 5 (0.1) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Laryngitis | 1 (0.0) | 2 (0.0) |
| Latent tuberculosis | 4 (0.1) | 3 (0.1) |
| Localised infection | 0 | 3 (0.1) |
| Ludwig angina | 1 (0.0) | 0 |
| Lyme disease | 5 (0.1) | 6 (0.1) |
| Lymph gland infection | 2 (0.0) | 0 |
| Meningitis | 2 (0.0) | 4 (0.1) |
| Meningitis aseptic | 1 (0.0) | 0 |
| Meningitis viral | 2 (0.0) | 1 (0.0) |
| Mycobacterium avium complex infection | 0 | 1 (0.0) |
| Nail infection | 1 (0.0) | 0 |
| Nasopharyngitis | 0 | 1 (0.0) |
| Oesophagitis bacterial | 0 | 1 (0.0) |
| Onychomycosis | 27 (0.5) | 19 (0.4) |
| Oral candidiasis | 0 | 2 (0.0) |
| Oral herpes | 36 (0.7) | 43 (0.9) |
| Orchitis | 0 | 1 (0.0) |
| Osteomyelitis | 3 (0.1) | 6 (0.1) |
| Osteomyelitis chronic | 1 (0.0) | 0 |
| Otitis externa | 2 (0.0) | 1 (0.0) |
| Otitis externa fungal | 0 | 1 (0.0) |
| Otitis media | 7 (0.1) | 3 (0.1) |
| Otitis media acute | 0 | 2 (0.0) |
| Otitis media chronic | 3 (0.1) | 2 (0.0) |
| Papilloma viral infection | 4 (0.1) | 1 (0.0) |
| Paronychia | 1 (0.0) | 0 |
| Parotitis | 1 (0.0) | 1 (0.0) |
| Pelvic abscess | 1 (0.0) | 0 |
| Pelvic inflammatory disease | 2 (0.0) | 2 (0.0) |
| Periodontal destruction | 1 (0.0) | 0 |
| Peritonitis | 1 (0.0) | 2 (0.0) |
| Peritonsillar abscess | 0 | 1 (0.0) |
| Pertussis | 0 | 1 (0.0) |
| Pharyngitis | 3 (0.1) | 0 |
| Pharyngitis streptococcal | 2 (0.0) | 10 (0.2) |
| Pilonidal cyst | 8 (0.2) | 3 (0.1) |
| Plasmodium falciparum infection | 0 | 1 (0.0) |
| Pneumonia | 33 (0.6) | 28 (0.6) |
| Pneumonia adenoviral | 0 | 1 (0.0) |
| Pneumonia aspiration | 0 | 1 (0.0) |
| Pneumonia bacterial | 1 (0.0) | 0 |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Pneumonia viral | 1 (0.0) | 0 |
| Poliomyelitis | 4 (0.1) | 2 (0.0) |
| Postoperative abscess | 1 (0.0) | 0 |
| Postoperative wound infection | 0 | 1 (0.0) |
| Pulmonary tuberculosis | 1 (0.0) | 3 (0.1) |
| Pyelonephritis | 1 (0.0) | 0 |
| Pyelonephritis acute | 1 (0.0) | 0 |
| Rectal abscess | 1 (0.0) | 0 |
| Renal abscess | 1 (0.0) | 0 |
| Respiratory syncytial virus infection | 1 (0.0) | 0 |
| Respiratory tract infection | 1 (0.0) | 0 |
| Respiratory tract infection viral | 1 (0.0) | 0 |
| Rhinitis | 9 (0.2) | 15 (0.3) |
| Rhinovirus infection | 0 | 1 (0.0) |
| Salpingitis | 1 (0.0) | 0 |
| Scarlet fever | 1 (0.0) | 1 (0.0) |
| Scrotal infection | 1 (0.0) | 0 |
| Sepsis | 3 (0.1) | 3 (0.1) |
| Septic arthritis staphylococcal | 1 (0.0) | 0 |
| Sinusitis | 48 (0.9) | 29 (0.6) |
| Sinusitis bacterial | 1 (0.0) | 0 |
| Sinusitis fungal | 1 (0.0) | 0 |
| Skin bacterial infection | 1 (0.0) | 0 |
| Staphylococcal infection | 6 (0.1) | 5 (0.1) |
| Staphylococcal skin infection | 2 (0.0) | 1 (0.0) |
| Streptococcal infection | 2 (0.0) | 5 (0.1) |
| Subacute endocarditis | 1 (0.0) | 0 |
| Syphilis | 2 (0.0) | 4 (0.1) |
| Tinea cruris | 0 | 2 (0.0) |
| Tinea pedis | 3 (0.1) | 7 (0.1) |
| Tinea versicolour | 4 (0.1) | 5 (0.1) |
| Tonsillitis | 174 (3.4) | 153 (3.0) |
| Tooth abscess | 2 (0.0) | 5 (0.1) |
| Tooth infection | 1 (0.0) | 1 (0.0) |
| Toxic shock syndrome | 0 | 2 (0.0) |
| Trichomoniasis | 0 | 1 (0.0) |
| Tropical ulcer | 1 (0.0) | 0 |
| Tuberculosis | 5 (0.1) | 2 (0.0) |
| Tuberculous pleurisy | 1 (0.0) | 0 |
| Typhus | 0 | 1 (0.0) |
| Upper respiratory tract infection | 3 (0.1) | 4 (0.1) |

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| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Urethritis | 0 | 1 (0.0) |
| Urinary tract infection | 51 (1.0) | 40 (0.8) |
| Urinary tract infection bacterial | 0 | 1 (0.0) |
| Urosepsis | 0 | 1 (0.0) |
| Vaginal infection | 0 | 3 (0.1) |
| Vaginitis chlamydial | 3 (0.1) | 0 |
| Varicella | 3 (0.1) | 3 (0.1) |
| Varicella zoster virus infection | 1 (0.0) | 0 |
| Vestibular neuronitis | 1 (0.0) | 0 |
| Vulval abscess | 0 | 1 (0.0) |
| Vulvitis | 1 (0.0) | 0 |
| Vulvovaginal candidiasis | 1 (0.0) | 1 (0.0) |
| Vulvovaginal mycotic infection | 2 (0.0) | 2 (0.0) |
| Wound infection | 1 (0.0) | 0 |
| Injury, poisoning and procedural complications | 545 (10.7) | 543 (10.8) |
| Accident | 1 (0.0) | 1 (0.0) |
| Animal bite | 0 | 3 (0.1) |
| Animal scratch | 0 | 1 (0.0) |
| Ankle fracture | 29 (0.6) | 41 (0.8) |
| Arthropod bite | 4 (0.1) | 0 |
| Arthropod sting | 0 | 2 (0.0) |
| Back injury | 6 (0.1) | 11 (0.2) |
| Bite | 0 | 1 (0.0) |
| Blindness traumatic | 0 | 1 (0.0) |
| Brachial plexus injury | 0 | 1 (0.0) |
| Burns second degree | 1 (0.0) | 1 (0.0) |
| Cartilage injury | 21 (0.4) | 16 (0.3) |
| Cervical vertebral fracture | 3 (0.1) | 5 (0.1) |
| Chest injury | 2 (0.0) | 1 (0.0) |
| Clavicle fracture | 19 (0.4) | 6 (0.1) |
| Compression fracture | 1 (0.0) | 0 |
| Concussion | 6 (0.1) | 9 (0.2) |
| Contusion | 4 (0.1) | 0 |
| Craniocerebral injury | 3 (0.1) | 2 (0.0) |
| Decompression sickness | 0 | 1 (0.0) |
| Donor site complication | 1 (0.0) | 0 |
| Epicondylitis | 5 (0.1) | 9 (0.2) |
| Exposure to communicable disease | 1 (0.0) | 0 |
| Eye injury | 3 (0.1) | 1 (0.0) |
| Eyeball avulsion | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Face injury | 0 | 1 (0.0) |
| Facial bones fracture | 14 (0.3) | 16 (0.3) |
| Fall | 4 (0.1) | 8 (0.2) |
| Fascial rupture | 1 (0.0) | 0 |
| Femoral neck fracture | 0 | 1 (0.0) |
| Femur fracture | 16 (0.3) | 12 (0.2) |
| Fibula fracture | 7 (0.1) | 7 (0.1) |
| Foot fracture | 24 (0.5) | 28 (0.6) |
| Forearm fracture | 3 (0.1) | 5 (0.1) |
| Foreign body | 0 | 3 (0.1) |
| Foreign body in gastrointestinal tract | 1 (0.0) | 0 |
| Fracture | 2 (0.0) | 1 (0.0) |
| Fractured coccyx | 1 (0.0) | 0 |
| Gun shot wound | 3 (0.1) | 3 (0.1) |
| Hand fracture | 21 (0.4) | 26 (0.5) |
| Head injury | 3 (0.1) | 6 (0.1) |
| Hip fracture | 7 (0.1) | 5 (0.1) |
| Humerus fracture | 5 (0.1) | 5 (0.1) |
| Iatrogenic injury | 0 | 1 (0.0) |
| Iliotibial band syndrome | 1 (0.0) | 1 (0.0) |
| Incisional hernia | 5 (0.1) | 1 (0.0) |
| Injury | 1 (0.0) | 0 |
| Intervertebral disc injury | 1 (0.0) | 1 (0.0) |
| Iris injury | 1 (0.0) | 0 |
| Jaw fracture | 5 (0.1) | 6 (0.1) |
| Joint dislocation | 22 (0.4) | 15 (0.3) |
| Joint injury | 23 (0.5) | 19 (0.4) |
| Ligament injury | 4 (0.1) | 6 (0.1) |
| Ligament rupture | 61 (1.2) | 58 (1.1) |
| Ligament sprain | 11 (0.2) | 9 (0.2) |
| Limb crushing injury | 3 (0.1) | 2 (0.0) |
| Limb fracture | 3 (0.1) | 0 |
| Limb injury | 24 (0.5) | 18 (0.4) |
| Limb traumatic amputation | 0 | 1 (0.0) |
| Lip injury | 0 | 1 (0.0) |
| Lisfranc fracture | 0 | 1 (0.0) |
| Lower limb fracture | 15 (0.3) | 15 (0.3) |
| Lumbar vertebral fracture | 6 (0.1) | 6 (0.1) |
| Maisonneuve fracture | 0 | 1 (0.0) |
| Mallet finger | 0 | 1 (0.0) |
| Meniscus injury | 75 (1.5) | 78 (1.5) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Multiple fractures | 1 (0.0) | 0 |
| Muscle injury | 1 (0.0) | 2 (0.0) |
| Muscle rupture | 14 (0.3) | 8 (0.2) |
| Muscle strain | 6 (0.1) | 6 (0.1) |
| Musculoskeletal foreign body | 0 | 1 (0.0) |
| Nasal injury | 0 | 3 (0.1) |
| Neck injury | 0 | 2 (0.0) |
| Nerve injury | 4 (0.1) | 5 (0.1) |
| Neurological procedural complication | 0 | 1 (0.0) |
| Oesophageal injury | 0 | 1 (0.0) |
| Optic nerve injury | 0 | 1 (0.0) |
| Patella fracture | 4 (0.1) | 5 (0.1) |
| Pelvic fracture | 3 (0.1) | 3 (0.1) |
| Penetrating abdominal trauma | 1 (0.0) | 1 (0.0) |
| Periorbital haemorrhage | 1 (0.0) | 0 |
| Peripheral nerve injury | 1 (0.0) | 1 (0.0) |
| Post concussion syndrome | 1 (0.0) | 0 |
| Post procedural complication | 0 | 2 (0.0) |
| Post procedural diarrhoea | 0 | 1 (0.0) |
| Post procedural hypothyroidism | 6 (0.1) | 3 (0.1) |
| Post-traumatic neck syndrome | 1 (0.0) | 0 |
| Post-traumatic pain | 1 (0.0) | 0 |
| Postoperative adhesion | 1 (0.0) | 0 |
| Procedural complication | 0 | 1 (0.0) |
| Procedural pain | 1 (0.0) | 1 (0.0) |
| Radius fracture | 9 (0.2) | 6 (0.1) |
| Repetitive strain injury | 2 (0.0) | 0 |
| Respiratory fume inhalation disorder | 1 (0.0) | 0 |
| Rib fracture | 4 (0.1) | 9 (0.2) |
| Road traffic accident | 16 (0.3) | 13 (0.3) |
| Scapula fracture | 0 | 1 (0.0) |
| Scar | 10 (0.2) | 13 (0.3) |
| Sciatic nerve injury | 3 (0.1) | 0 |
| Seroma | 0 | 1 (0.0) |
| Sinus barotrauma | 0 | 1 (0.0) |
| Skeletal injury | 5 (0.1) | 3 (0.1) |
| Skin abrasion | 0 | 3 (0.1) |
| Skin injury | 0 | 1 (0.0) |
| Skin laceration | 8 (0.2) | 3 (0.1) |
| Skull fracture | 0 | 2 (0.0) |
| Skull fractured base | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Snake bite | 1 (0.0) | 1 (0.0) |
| Soft tissue injury | 0 | 1 (0.0) |
| Spinal column injury | 2 (0.0) | 3 (0.1) |
| Spinal compression fracture | 5 (0.1) | 7 (0.1) |
| Spinal cord injury | 1 (0.0) | 1 (0.0) |
| Spinal cord injury cervical | 2 (0.0) | 0 |
| Spinal fracture | 6 (0.1) | 1 (0.0) |
| Splenic injury | 1 (0.0) | 0 |
| Splenic rupture | 3 (0.1) | 0 |
| Sports injury | 1 (0.0) | 1 (0.0) |
| Stab wound | 0 | 2 (0.0) |
| Sternal fracture | 1 (0.0) | 0 |
| Stress fracture | 4 (0.1) | 2 (0.0) |
| Subarachnoid haematoma | 0 | 1 (0.0) |
| Subdural haematoma | 1 (0.0) | 3 (0.1) |
| Suture related complication | 0 | 1 (0.0) |
| Tendon injury | 7 (0.1) | 5 (0.1) |
| Tendon rupture | 27 (0.5) | 18 (0.4) |
| Thermal burn | 0 | 1 (0.0) |
| Thermal burns of eye | 0 | 1 (0.0) |
| Thoracic vertebral fracture | 0 | 1 (0.0) |
| Tibia fracture | 9 (0.2) | 13 (0.3) |
| Tooth fracture | 0 | 3 (0.1) |
| Traumatic arthritis | 1 (0.0) | 1 (0.0) |
| Traumatic ear amputation | 0 | 1 (0.0) |
| Traumatic lung injury | 0 | 1 (0.0) |
| Traumatic renal injury | 1 (0.0) | 1 (0.0) |
| Ulna fracture | 3 (0.1) | 0 |
| Upper limb fracture | 21 (0.4) | 26 (0.5) |
| Ureteric injury | 0 | 1 (0.0) |
| Uterine rupture | 2 (0.0) | 1 (0.0) |
| Vascular pseudoaneurysm | 1 (0.0) | 0 |
| Vitreous injury | 1 (0.0) | 0 |
| Vth nerve injury | 0 | 1 (0.0) |
| Wound | 0 | 1 (0.0) |
| Wrist fracture | 31 (0.6) | 31 (0.6) |
| Investigations | 517 (10.2) | 522 (10.3) |
| Alanine aminotransferase increased | 0 | 2 (0.0) |
| Angiocardiogram | 2 (0.0) | 0 |
| Angiogram | 1 (0.0) | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Anti-thyroid antibody positive | 0 | 1 (0.0) |
| Antinuclear antibody positive | 0 | 1 (0.0) |
| Antiphospholipid antibodies positive | 0 | 1 (0.0) |
| Apolipoprotein E | 1 (0.0) | 0 |
| Arthroscopy | 49 (1.0) | 42 (0.8) |
| Aspiration joint | 0 | 1 (0.0) |
| Barium swallow | 1 (0.0) | 0 |
| Biopsy | 1 (0.0) | 2 (0.0) |
| Biopsy bone | 0 | 1 (0.0) |
| Biopsy breast | 18 (0.4) | 17 (0.3) |
| Biopsy breast normal | 2 (0.0) | 6 (0.1) |
| Biopsy cervix abnormal | 0 | 1 (0.0) |
| Biopsy cervix normal | 0 | 1 (0.0) |
| Biopsy colon | 2 (0.0) | 1 (0.0) |
| Biopsy endometrium normal | 1 (0.0) | 0 |
| Biopsy liver | 1 (0.0) | 1 (0.0) |
| Biopsy liver normal | 1 (0.0) | 0 |
| Biopsy lung | 1 (0.0) | 3 (0.1) |
| Biopsy lymph gland | 3 (0.1) | 1 (0.0) |
| Biopsy prostate | 1 (0.0) | 2 (0.0) |
| Biopsy prostate normal | 1 (0.0) | 0 |
| Biopsy salivary gland | 0 | 1 (0.0) |
| Biopsy site unspecified normal | 1 (0.0) | 0 |
| Biopsy skin | 2 (0.0) | 3 (0.1) |
| Biopsy skin abnormal | 0 | 1 (0.0) |
| Biopsy testes | 0 | 1 (0.0) |
| Biopsy thyroid gland | 1 (0.0) | 1 (0.0) |
| Biopsy uterus | 0 | 1 (0.0) |
| Blood bilirubin increased | 1 (0.0) | 0 |
| Blood calcium decreased | 0 | 1 (0.0) |
| Blood calcium increased | 0 | 1 (0.0) |
| Blood cholesterol | 2 (0.0) | 0 |
| Blood cholesterol increased | 208 (4.1) | 197 (3.9) |
| Blood creatinine abnormal | 0 | 1 (0.0) |
| Blood glucose | 1 (0.0) | 0 |
| Blood glucose abnormal | 0 | 1 (0.0) |
| Blood glucose increased | 3 (0.1) | 3 (0.1) |
| Blood iron decreased | 0 | 2 (0.0) |
| Blood luteinising hormone abnormal | 1 (0.0) | 0 |
| Blood oestrogen decreased | 1 (0.0) | 1 (0.0) |
| Blood oestrogen increased | 1 (0.0) | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Blood parathyroid hormone abnormal | 1 (0.0) | 0 |
| Blood potassium decreased | 0 | 1 (0.0) |
| Blood pressure increased | 4 (0.1) | 3 (0.1) |
| Blood testosterone decreased | 36 (0.7) | 40 (0.8) |
| Blood testosterone increased | 0 | 2 (0.0) |
| Blood thyroid stimulating hormone abnormal | 0 | 1 (0.0) |
| Blood thyroid stimulating hormone decreased | 1 (0.0) | 0 |
| Blood triglycerides | 1 (0.0) | 0 |
| Blood triglycerides increased | 22 (0.4) | 17 (0.3) |
| Blood uric acid increased | 0 | 2 (0.0) |
| Body mass index increased | 1 (0.0) | 0 |
| Bronchoscopy | 0 | 2 (0.0) |
| Bronchoscopy abnormal | 0 | 1 (0.0) |
| C-reactive protein increased | 0 | 1 (0.0) |
| Cardiac murmur | 29 (0.6) | 38 (0.8) |
| Cardiac murmur functional | 1 (0.0) | 2 (0.0) |
| Catheterisation cardiac | 16 (0.3) | 12 (0.2) |
| Clostridium test positive | 0 | 1 (0.0) |
| Colonoscopy | 41 (0.8) | 52 (1.0) |
| Colonoscopy normal | 1 (0.0) | 1 (0.0) |
| Colposcopy | 0 | 2 (0.0) |
| Cystoscopy | 1 (0.0) | 2 (0.0) |
| Cytology abnormal | 1 (0.0) | 0 |
| Dehydroepiandrosterone decreased | 1 (0.0) | 0 |
| Diagnostic procedure | 1 (0.0) | 0 |
| Echocardiogram | 1 (0.0) | 0 |
| Ejection fraction abnormal | 1 (0.0) | 0 |
| Ejection fraction decreased | 1 (0.0) | 1 (0.0) |
| Electrocardiogram QT prolonged | 1 (0.0) | 0 |
| Electrocardiogram ST segment abnormal | 0 | 1 (0.0) |
| Electrocardiogram T wave inversion | 1 (0.0) | 0 |
| Electrocardiogram abnormal | 2 (0.0) | 0 |
| Endoscopic retrograde cholangiopancreatography | 0 | 1 (0.0) |
| Endoscopy | 7 (0.1) | 5 (0.1) |
| Endoscopy gastrointestinal | 0 | 1 (0.0) |
| Endoscopy upper gastrointestinal tract | 4 (0.1) | 5 (0.1) |
| Full blood count | 1 (0.0) | 0 |
| Gene mutation identification test positive | 0 | 1 (0.0) |
| Glomerular filtration rate | 0 | 1 (0.0) |
| Glycosylated haemoglobin | 1 (0.0) | 0 |
| Glycosylated haemoglobin increased | 1 (0.0) | 0 |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| HIV test positive | 18 (0.4) | 19 (0.4) |
| HLA marker study | 0 | 1 (0.0) |
| HLA-B*27 positive | 0 | 1 (0.0) |
| Heart rate decreased | 1 (0.0) | 1 (0.0) |
| Heart rate increased | 0 | 2 (0.0) |
| Heart rate irregular | 6 (0.1) | 7 (0.1) |
| Hepatic enzyme increased | 2 (0.0) | 5 (0.1) |
| Hepatitis C antibody positive | 1 (0.0) | 1 (0.0) |
| High density lipoprotein decreased | 2 (0.0) | 3 (0.1) |
| Hormone level abnormal | 4 (0.1) | 4 (0.1) |
| Human papilloma virus test positive | 7 (0.1) | 11 (0.2) |
| Hysteroscopy | 2 (0.0) | 4 (0.1) |
| International normalised ratio | 0 | 1 (0.0) |
| Intraocular pressure increased | 3 (0.1) | 3 (0.1) |
| Laparoscopy | 8 (0.2) | 7 (0.1) |
| Lipids | 1 (0.0) | 0 |
| Lipids increased | 2 (0.0) | 3 (0.1) |
| Lipoprotein (a) abnormal | 1 (0.0) | 0 |
| Liver function test abnormal | 0 | 1 (0.0) |
| Liver function test increased | 2 (0.0) | 2 (0.0) |
| Low density lipoprotein increased | 3 (0.1) | 0 |
| Lumbar puncture | 1 (0.0) | 0 |
| Lymphocyte count increased | 0 | 1 (0.0) |
| Mammogram abnormal | 2 (0.0) | 3 (0.1) |
| Mediastinoscopy | 2 (0.0) | 0 |
| Medical observation | 1 (0.0) | 0 |
| Metabolic function test | 1 (0.0) | 0 |
| Mycobacterium tuberculosis complex test positive | 1 (0.0) | 0 |
| Nasoendoscopy | 0 | 2 (0.0) |
| Oesophagogastroduodenoscopy | 2 (0.0) | 1 (0.0) |
| Oestradiol decreased | 0 | 1 (0.0) |
| Panendoscopy | 0 | 1 (0.0) |
| Pelvic laparoscopy | 0 | 3 (0.1) |
| Precancerous cells present | 4 (0.1) | 2 (0.0) |
| Progesterone decreased | 2 (0.0) | 0 |
| Prostatic specific antigen abnormal | 0 | 1 (0.0) |
| Prostatic specific antigen increased | 6 (0.1) | 9 (0.2) |
| Rheumatoid factor positive | 1 (0.0) | 0 |
| SARS-CoV-2 antibody test positive | 2 (0.0) | 2 (0.0) |
| SARS-CoV-2 test positive | 0 | 1 (0.0) |
| Scan myocardial perfusion | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Seroconversion test positive | 1 (0.0) | 0 |
| Serum ferritin increased | 0 | 1 (0.0) |
| Sigmoidoscopy | 0 | 1 (0.0) |
| Sleep study | 2 (0.0) | 0 |
| Smear cervix abnormal | 4 (0.1) | 6 (0.1) |
| Staphylococcus test positive | 0 | 1 (0.0) |
| Stool analysis abnormal | 1 (0.0) | 0 |
| Transaminases increased | 2 (0.0) | 0 |
| Tuberculin test positive | 3 (0.1) | 8 (0.2) |
| Ureteroscopy | 1 (0.0) | 0 |
| Vitamin B12 decreased | 0 | 2 (0.0) |
| Vitamin D decreased | 5 (0.1) | 4 (0.1) |
| Weight decreased | 1 (0.0) | 4 (0.1) |
| Weight increased | 2 (0.0) | 1 (0.0) |
| White blood cell count increased | 0 | 1 (0.0) |
| Metabolism and nutrition disorders | 1822 (35.9) | 1845 (36.6) |
| Abnormal loss of weight | 0 | 1 (0.0) |
| Calcium deficiency | 1 (0.0) | 1 (0.0) |
| Central obesity | 0 | 1 (0.0) |
| Cholesterosis | 0 | 2 (0.0) |
| Dairy intolerance | 2 (0.0) | 1 (0.0) |
| Decreased appetite | 2 (0.0) | 0 |
| Dehydration | 2 (0.0) | 1 (0.0) |
| Diabetes mellitus | 6 (0.1) | 7 (0.1) |
| Diabetes mellitus inadequate control | 1 (0.0) | 0 |
| Diabetic dyslipidaemia | 1 (0.0) | 2 (0.0) |
| Diabetic ketoacidosis | 2 (0.0) | 0 |
| Disaccharide metabolism disorder | 1 (0.0) | 0 |
| Dyslipidaemia | 130 (2.6) | 135 (2.7) |
| Electrolyte imbalance | 1 (0.0) | 0 |
| Fluid retention | 7 (0.1) | 8 (0.2) |
| Folate deficiency | 1 (0.0) | 0 |
| Food intolerance | 3 (0.1) | 1 (0.0) |
| Glucose tolerance impaired | 75 (1.5) | 81 (1.6) |
| Gluten sensitivity | 7 (0.1) | 7 (0.1) |
| Gout | 77 (1.5) | 85 (1.7) |
| Haemochromatosis | 6 (0.1) | 1 (0.0) |
| Hyperamylasaemia | 1 (0.0) | 0 |
| Hypercalcaemia | 3 (0.1) | 6 (0.1) |
| Hypercholesterolaemia | 470 (9.3) | 476 (9.4) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Hyperglycaemia | 7 (0.1) | 5 (0.1) |
| Hyperhomocysteinaemia | 0 | 2 (0.0) |
| Hyperinsulinism | 0 | 1 (0.0) |
| Hyperkalaemia | 0 | 1 (0.0) |
| Hyperlipidaemia | 436 (8.6) | 414 (8.2) |
| Hyperphagia | 0 | 1 (0.0) |
| Hyperphosphataemia | 1 (0.0) | 1 (0.0) |
| Hypertriglyceridaemia | 48 (0.9) | 21 (0.4) |
| Hyperuricaemia | 5 (0.1) | 7 (0.1) |
| Hypocalcaemia | 1 (0.0) | 0 |
| Hypocholesterolaemia | 2 (0.0) | 5 (0.1) |
| Hypoglycaemia | 4 (0.1) | 7 (0.1) |
| Hypokalaemia | 14 (0.3) | 14 (0.3) |
| Hypolipidaemia | 0 | 1 (0.0) |
| Hypomagnesaemia | 2 (0.0) | 1 (0.0) |
| Hyponatraemia | 3 (0.1) | 0 |
| Hypophosphataemia | 3 (0.1) | 0 |
| Hypovitaminosis | 0 | 1 (0.0) |
| Impaired fasting glucose | 11 (0.2) | 7 (0.1) |
| Insulin resistance | 2 (0.0) | 7 (0.1) |
| Iron deficiency | 5 (0.1) | 15 (0.3) |
| Lactose intolerance | 16 (0.3) | 31 (0.6) |
| Latent autoimmune diabetes in adults | 1 (0.0) | 0 |
| Magnesium deficiency | 2 (0.0) | 0 |
| Malnutrition | 0 | 1 (0.0) |
| Metabolic syndrome | 7 (0.1) | 1 (0.0) |
| Obesity | 511 (10.1) | 508 (10.1) |
| Overweight | 83 (1.6) | 110 (2.2) |
| Polydipsia | 1 (0.0) | 0 |
| Postprandial hypoglycaemia | 1 (0.0) | 0 |
| Refeeding syndrome | 0 | 1 (0.0) |
| Type 1 diabetes mellitus | 18 (0.4) | 18 (0.4) |
| Type 2 diabetes mellitus | 395 (7.8) | 400 (7.9) |
| Vitamin A deficiency | 1 (0.0) | 0 |
| Vitamin B complex deficiency | 4 (0.1) | 6 (0.1) |
| Vitamin B12 deficiency | 27 (0.5) | 30 (0.6) |
| Vitamin D deficiency | 135 (2.7) | 122 (2.4) |
| Vitamin K deficiency | 1 (0.0) | 0 |
| Musculoskeletal and connective tissue disorders | 1391 (27.4) | 1306 (25.9) |
| Ankylosing spondylitis | 5 (0.1) | 2 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Arthralgia | 163 (3.2) | 138 (2.7) |
| Arthritis | 84 (1.7) | 94 (1.9) |
| Arthritis reactive | 1 (0.0) | 0 |
| Arthropathy | 6 (0.1) | 5 (0.1) |
| Back disorder | 2 (0.0) | 1 (0.0) |
| Back pain | 270 (5.3) | 232 (4.6) |
| Bone cyst | 2 (0.0) | 2 (0.0) |
| Bone disorder | 1 (0.0) | 0 |
| Bone erosion | 0 | 1 (0.0) |
| Bone lesion | 2 (0.0) | 0 |
| Bone pain | 1 (0.0) | 0 |
| Bursitis | 20 (0.4) | 14 (0.3) |
| CREST syndrome | 0 | 1 (0.0) |
| Cervical spinal stenosis | 2 (0.0) | 4 (0.1) |
| Chondromalacia | 2 (0.0) | 0 |
| Chondropathy | 5 (0.1) | 0 |
| Coccydynia | 1 (0.0) | 1 (0.0) |
| Compartment syndrome | 1 (0.0) | 1 (0.0) |
| Costochondritis | 1 (0.0) | 1 (0.0) |
| Diastasis recti abdominis | 2 (0.0) | 0 |
| Diffuse idiopathic skeletal hyperostosis | 0 | 1 (0.0) |
| Dupuytren's contracture | 4 (0.1) | 5 (0.1) |
| Dwarfism | 1 (0.0) | 0 |
| Enthesopathy | 1 (0.0) | 0 |
| Exostosis | 14 (0.3) | 23 (0.5) |
| Facet joint syndrome | 1 (0.0) | 2 (0.0) |
| Femoroacetabular impingement | 1 (0.0) | 0 |
| Fibromyalgia | 40 (0.8) | 47 (0.9) |
| Fistula | 0 | 1 (0.0) |
| Flank pain | 0 | 1 (0.0) |
| Floating patella | 1 (0.0) | 0 |
| Foot deformity | 39 (0.8) | 41 (0.8) |
| Groin pain | 0 | 1 (0.0) |
| Hypermobility syndrome | 1 (0.0) | 0 |
| Inclusion body myositis | 0 | 1 (0.0) |
| Intervertebral disc compression | 4 (0.1) | 2 (0.0) |
| Intervertebral disc degeneration | 54 (1.1) | 54 (1.1) |
| Intervertebral disc disorder | 5 (0.1) | 1 (0.0) |
| Intervertebral disc displacement | 1 (0.0) | 1 (0.0) |
| Intervertebral disc protrusion | 76 (1.5) | 77 (1.5) |
| Jaw disorder | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Joint instability | 1 (0.0) | 2 (0.0) |
| Joint range of motion decreased | 4 (0.1) | 1 (0.0) |
| Joint stiffness | 2 (0.0) | 1 (0.0) |
| Joint swelling | 3 (0.1) | 5 (0.1) |
| Knee deformity | 1 (0.0) | 0 |
| Kyphoscoliosis | 1 (0.0) | 0 |
| Kyphosis | 2 (0.0) | 3 (0.1) |
| Ligament disorder | 1 (0.0) | 1 (0.0) |
| Limb asymmetry | 1 (0.0) | 1 (0.0) |
| Limb deformity | 0 | 1 (0.0) |
| Limb mass | 1 (0.0) | 0 |
| Lumbar spinal stenosis | 9 (0.2) | 7 (0.1) |
| Muscle atrophy | 0 | 1 (0.0) |
| Muscle spasms | 45 (0.9) | 30 (0.6) |
| Muscle tightness | 1 (0.0) | 0 |
| Muscular weakness | 1 (0.0) | 6 (0.1) |
| Musculoskeletal chest pain | 1 (0.0) | 4 (0.1) |
| Musculoskeletal pain | 1 (0.0) | 3 (0.1) |
| Musculoskeletal stiffness | 2 (0.0) | 2 (0.0) |
| Myalgia | 32 (0.6) | 39 (0.8) |
| Myofascial pain syndrome | 1 (0.0) | 1 (0.0) |
| Neck mass | 1 (0.0) | 0 |
| Neck pain | 40 (0.8) | 28 (0.6) |
| Neuropathic arthropathy | 0 | 1 (0.0) |
| Os trigonum syndrome | 0 | 1 (0.0) |
| Osteitis deformans | 0 | 1 (0.0) |
| Osteoarthritis | 470 (9.3) | 449 (8.9) |
| Osteochondritis | 0 | 1 (0.0) |
| Osteochondrosis | 0 | 2 (0.0) |
| Osteolysis | 0 | 1 (0.0) |
| Osteomalacia | 0 | 1 (0.0) |
| Osteonecrosis | 3 (0.1) | 3 (0.1) |
| Osteopenia | 90 (1.8) | 91 (1.8) |
| Osteoporosis | 98 (1.9) | 97 (1.9) |
| Osteosclerosis | 1 (0.0) | 0 |
| Pain in extremity | 28 (0.6) | 23 (0.5) |
| Pain in jaw | 2 (0.0) | 2 (0.0) |
| Patellofemoral pain syndrome | 2 (0.0) | 3 (0.1) |
| Pathological fracture | 1 (0.0) | 0 |
| Periarthritis | 11 (0.2) | 5 (0.1) |
| Perthes disease | 1 (0.0) | 0 |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Plantar fascial fibromatosis | 1 (0.0) | 0 |
| Plantar fasciitis | 18 (0.4) | 19 (0.4) |
| Plica syndrome | 0 | 1 (0.0) |
| Polyarthritis | 2 (0.0) | 3 (0.1) |
| Polymyalgia rheumatica | 1 (0.0) | 1 (0.0) |
| Posterior tibial tendon dysfunction | 0 | 1 (0.0) |
| Psoriatic arthropathy | 2 (0.0) | 2 (0.0) |
| Rheumatic disorder | 0 | 1 (0.0) |
| Rheumatic fever | 2 (0.0) | 0 |
| Rheumatoid arthritis | 11 (0.2) | 10 (0.2) |
| Rotator cuff syndrome | 101 (2.0) | 74 (1.5) |
| Sacral pain | 2 (0.0) | 0 |
| Sacroiliac joint dysfunction | 2 (0.0) | 0 |
| Scleroderma | 0 | 1 (0.0) |
| Scoliosis | 24 (0.5) | 27 (0.5) |
| Seronegative arthritis | 0 | 1 (0.0) |
| Short stature | 1 (0.0) | 0 |
| Sjogren's syndrome | 3 (0.1) | 4 (0.1) |
| Spinal deformity | 0 | 1 (0.0) |
| Spinal disorder | 1 (0.0) | 1 (0.0) |
| Spinal osteoarthritis | 66 (1.3) | 54 (1.1) |
| Spinal pain | 2 (0.0) | 3 (0.1) |
| Spinal stenosis | 27 (0.5) | 23 (0.5) |
| Spinal synovial cyst | 1 (0.0) | 0 |
| Spondylitis | 10 (0.2) | 7 (0.1) |
| Spondyloarthropathy | 3 (0.1) | 1 (0.0) |
| Spondylolisthesis | 12 (0.2) | 1 (0.0) |
| Spondylolysis | 3 (0.1) | 0 |
| Symphysiolysis | 0 | 1 (0.0) |
| Synovial cyst | 16 (0.3) | 8 (0.2) |
| Systemic lupus erythematosus | 2 (0.0) | 3 (0.1) |
| Temporomandibular joint syndrome | 20 (0.4) | 7 (0.1) |
| Tendon disorder | 3 (0.1) | 1 (0.0) |
| Tendonitis | 21 (0.4) | 17 (0.3) |
| Tenosynovitis | 1 (0.0) | 0 |
| Tenosynovitis stenosans | 1 (0.0) | 5 (0.1) |
| Torticollis | 1 (0.0) | 0 |
| Trigger finger | 19 (0.4) | 17 (0.3) |
| Ulnocarpal abutment syndrome | 1 (0.0) | 0 |
| Vertebral foraminal stenosis | 0 | 1 (0.0) |
| Vertebral osteophyte | 2 (0.0) | 2 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 601 (11.8) | 594 (11.8) |
| 5q minus syndrome | 1 (0.0) | 0 |
| Acanthoma | 1 (0.0) | 0 |
| Acoustic neuroma | 3 (0.1) | 1 (0.0) |
| Acute myeloid leukaemia | 1 (0.0) | 1 (0.0) |
| Adenoid cystic carcinoma | 0 | 1 (0.0) |
| Adenoma benign | 2 (0.0) | 0 |
| Adrenal adenoma | 0 | 1 (0.0) |
| Adrenal neoplasm | 1 (0.0) | 1 (0.0) |
| Anal cancer | 0 | 1 (0.0) |
| Angiofibroma | 0 | 1 (0.0) |
| Anogenital warts | 0 | 2 (0.0) |
| Appendix cancer | 1 (0.0) | 1 (0.0) |
| Astrocytoma | 1 (0.0) | 0 |
| Basal cell carcinoma | 94 (1.9) | 112 (2.2) |
| Basosquamous carcinoma | 0 | 2 (0.0) |
| Benign bone neoplasm | 1 (0.0) | 1 (0.0) |
| Benign breast neoplasm | 10 (0.2) | 20 (0.4) |
| Benign gastric neoplasm | 0 | 1 (0.0) |
| Benign gastrointestinal neoplasm | 0 | 1 (0.0) |
| Benign hydatidiform mole | 1 (0.0) | 0 |
| Benign joint neoplasm | 0 | 1 (0.0) |
| Benign lung neoplasm | 0 | 1 (0.0) |
| Benign mediastinal neoplasm | 1 (0.0) | 0 |
| Benign neoplasm | 4 (0.1) | 3 (0.1) |
| Benign neoplasm of bladder | 1 (0.0) | 0 |
| Benign neoplasm of skin | 3 (0.1) | 2 (0.0) |
| Benign neoplasm of thymus | 0 | 1 (0.0) |
| Benign neoplasm of thyroid gland | 4 (0.1) | 10 (0.2) |
| Benign ovarian tumour | 3 (0.1) | 0 |
| Benign pancreatic neoplasm | 0 | 1 (0.0) |
| Benign salivary gland neoplasm | 1 (0.0) | 1 (0.0) |
| Benign uterine neoplasm | 1 (0.0) | 0 |
| Bladder cancer | 5 (0.1) | 4 (0.1) |
| Bladder neoplasm | 1 (0.0) | 0 |
| Bladder transitional cell carcinoma | 0 | 1 (0.0) |
| Bone neoplasm | 2 (0.0) | 0 |
| Borderline serous tumour of ovary | 0 | 1 (0.0) |
| Brain neoplasm | 1 (0.0) | 1 (0.0) |
| Brain neoplasm benign | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Breast cancer | 52 (1.0) | 45 (0.9) |
| Breast cancer in situ | 3 (0.1) | 1 (0.0) |
| Breast cancer metastatic | 1 (0.0) | 0 |
| Breast cancer recurrent | 1 (0.0) | 0 |
| Breast cancer stage I | 2 (0.0) | 1 (0.0) |
| Breast fibroma | 1 (0.0) | 3 (0.1) |
| Breast neoplasm | 1 (0.0) | 2 (0.0) |
| Cervix carcinoma | 8 (0.2) | 10 (0.2) |
| Cervix carcinoma stage 0 | 1 (0.0) | 0 |
| Cholesteatoma | 1 (0.0) | 1 (0.0) |
| Chromophobe renal cell carcinoma | 0 | 1 (0.0) |
| Chronic lymphocytic leukaemia | 0 | 2 (0.0) |
| Colon adenoma | 10 (0.2) | 8 (0.2) |
| Colon cancer | 10 (0.2) | 9 (0.2) |
| Colorectal cancer | 0 | 1 (0.0) |
| Cutaneous B-cell lymphoma | 1 (0.0) | 0 |
| Desmoid tumour | 1 (0.0) | 0 |
| Desmoplastic melanoma | 1 (0.0) | 0 |
| Diffuse large B-cell lymphoma | 0 | 1 (0.0) |
| Dysplastic naevus | 2 (0.0) | 0 |
| Enchondromatosis | 0 | 1 (0.0) |
| Endometrial cancer | 7 (0.1) | 4 (0.1) |
| Endometrial cancer stage III | 1 (0.0) | 0 |
| Essential thrombocythaemia | 1 (0.0) | 0 |
| Extragonadal primary seminoma (pure) | 0 | 1 (0.0) |
| Eye naevus | 1 (0.0) | 1 (0.0) |
| Fibroadenoma of breast | 4 (0.1) | 2 (0.0) |
| Fibroma | 7 (0.1) | 3 (0.1) |
| Fibrous histiocytoma | 0 | 1 (0.0) |
| Follicular lymphoma | 0 | 1 (0.0) |
| Gallbladder cancer | 0 | 1 (0.0) |
| Ganglioneuroblastoma | 0 | 1 (0.0) |
| Gastric neoplasm | 0 | 1 (0.0) |
| Gestational trophoblastic tumour | 0 | 1 (0.0) |
| Haemangioma | 1 (0.0) | 1 (0.0) |
| Haemangioma of liver | 1 (0.0) | 0 |
| Haemangioma of skin | 3 (0.1) | 1 (0.0) |
| Hepatic adenoma | 0 | 1 (0.0) |
| Hepatic cancer | 0 | 1 (0.0) |
| Hodgkin's disease | 3 (0.1) | 1 (0.0) |
| Hypergammaglobulinaemia benign monoclonal | 0 | 2 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Intraductal proliferative breast lesion | 2 (0.0) | 1 (0.0) |
| Invasive breast carcinoma | 0 | 1 (0.0) |
| Invasive ductal breast carcinoma | 0 | 2 (0.0) |
| Juvenile melanoma benign | 1 (0.0) | 0 |
| Large granular lymphocytosis | 1 (0.0) | 0 |
| Large intestine benign neoplasm | 0 | 1 (0.0) |
| Laryngeal cancer | 1 (0.0) | 0 |
| Leiomyoma | 1 (0.0) | 2 (0.0) |
| Leukaemia | 0 | 2 (0.0) |
| Lip and/or oral cavity cancer | 3 (0.1) | 1 (0.0) |
| Lip squamous cell carcinoma | 1 (0.0) | 1 (0.0) |
| Lipoma | 23 (0.5) | 13 (0.3) |
| Lipoma of breast | 2 (0.0) | 0 |
| Lobular breast carcinoma in situ | 3 (0.1) | 0 |
| Lung neoplasm malignant | 4 (0.1) | 2 (0.0) |
| Lymphoma | 2 (0.0) | 1 (0.0) |
| Malignant melanoma | 35 (0.7) | 40 (0.8) |
| Malignant melanoma in situ | 4 (0.1) | 0 |
| Malignant melanoma of eyelid | 0 | 1 (0.0) |
| Malignant melanoma stage I | 0 | 1 (0.0) |
| Melanocytic naevus | 9 (0.2) | 7 (0.1) |
| Melanoma recurrent | 1 (0.0) | 0 |
| Meningioma | 4 (0.1) | 2 (0.0) |
| Meningioma benign | 1 (0.0) | 2 (0.0) |
| Metastatic neoplasm | 0 | 1 (0.0) |
| Mucoepidermoid carcinoma of salivary gland | 0 | 1 (0.0) |
| Nasopharyngeal cancer | 1 (0.0) | 0 |
| Neoplasm | 2 (0.0) | 0 |
| Neoplasm malignant | 1 (0.0) | 0 |
| Neoplasm of appendix | 0 | 1 (0.0) |
| Neoplasm skin | 2 (0.0) | 0 |
| Neuroma | 6 (0.1) | 6 (0.1) |
| Non-Hodgkin's lymphoma | 4 (0.1) | 1 (0.0) |
| Oesophageal adenocarcinoma | 0 | 2 (0.0) |
| Oesophageal carcinoma | 0 | 1 (0.0) |
| Oesophageal carcinoma stage 0 | 1 (0.0) | 0 |
| Oral neoplasm | 1 (0.0) | 0 |
| Oral papilloma | 1 (0.0) | 0 |
| Osteochondroma | 2 (0.0) | 0 |
| Osteoma | 0 | 1 (0.0) |
| Osteosarcoma | 1 (0.0) | 0 |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Ovarian adenoma | 0 | 1 (0.0) |
| Ovarian cancer | 4 (0.1) | 2 (0.0) |
| Ovarian cancer stage IV | 1 (0.0) | 0 |
| Ovarian dysgerminoma stage unspecified | 0 | 1 (0.0) |
| Ovarian germ cell teratoma benign | 1 (0.0) | 0 |
| Ovarian neoplasm | 1 (0.0) | 1 (0.0) |
| Papillary thyroid cancer | 3 (0.1) | 6 (0.1) |
| Papilloma | 1 (0.0) | 0 |
| Paranasal sinus benign neoplasm | 1 (0.0) | 0 |
| Parathyroid tumour | 0 | 1 (0.0) |
| Parathyroid tumour benign | 2 (0.0) | 2 (0.0) |
| Pharyngeal neoplasm | 1 (0.0) | 0 |
| Phyllodes tumour | 0 | 1 (0.0) |
| Pituitary tumour | 0 | 1 (0.0) |
| Pituitary tumour benign | 5 (0.1) | 2 (0.0) |
| Plasma cell myeloma | 1 (0.0) | 1 (0.0) |
| Polycythaemia vera | 1 (0.0) | 1 (0.0) |
| Prolactin-producing pituitary tumour | 1 (0.0) | 0 |
| Prostate cancer | 59 (1.2) | 53 (1.1) |
| Pyogenic granuloma | 1 (0.0) | 0 |
| Rectal cancer | 2 (0.0) | 0 |
| Rectal neoplasm | 1 (0.0) | 0 |
| Renal cancer | 2 (0.0) | 7 (0.1) |
| Renal cancer recurrent | 1 (0.0) | 0 |
| Renal cell carcinoma | 3 (0.1) | 1 (0.0) |
| Renal lipoma | 0 | 1 (0.0) |
| Retinoblastoma | 1 (0.0) | 0 |
| Schwannoma | 2 (0.0) | 2 (0.0) |
| Seborrhoeic keratosis | 11 (0.2) | 8 (0.2) |
| Sinonasal papilloma | 1 (0.0) | 0 |
| Skin cancer | 3 (0.1) | 6 (0.1) |
| Skin papilloma | 3 (0.1) | 4 (0.1) |
| Small intestine carcinoma | 0 | 1 (0.0) |
| Spinal cord neoplasm | 1 (0.0) | 0 |
| Squamous cell breast carcinoma | 0 | 1 (0.0) |
| Squamous cell carcinoma | 24 (0.5) | 33 (0.7) |
| Squamous cell carcinoma of lung | 0 | 1 (0.0) |
| Squamous cell carcinoma of skin | 28 (0.6) | 18 (0.4) |
| Squamous cell carcinoma of the tongue | 0 | 1 (0.0) |
| Squamous cell carcinoma of the vulva | 1 (0.0) | 0 |
| Synovial sarcoma | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| T-cell lymphoma | 1 (0.0) | 1 (0.0) |
| Teratoma | 1 (0.0) | 0 |
| Testis cancer | 5 (0.1) | 7 (0.1) |
| Throat cancer | 1 (0.0) | 1 (0.0) |
| Thymoma | 1 (0.0) | 0 |
| Thyroid adenoma | 1 (0.0) | 1 (0.0) |
| Thyroid cancer | 16 (0.3) | 10 (0.2) |
| Thyroid neoplasm | 1 (0.0) | 3 (0.1) |
| Tongue neoplasm malignant stage unspecified | 0 | 2 (0.0) |
| Tonsil cancer | 2 (0.0) | 1 (0.0) |
| Uterine cancer | 13 (0.3) | 7 (0.1) |
| Uterine leiomyoma | 130 (2.6) | 133 (2.6) |
| Vulval cancer | 0 | 1 (0.0) |
| Nervous system disorders | 905 (17.8) | 844 (16.7) |
| Ageusia | 1 (0.0) | 3 (0.1) |
| Amnesia | 9 (0.2) | 6 (0.1) |
| Angiopathic neuropathy | 1 (0.0) | 0 |
| Anosmia | 1 (0.0) | 1 (0.0) |
| Aphasia | 1 (0.0) | 1 (0.0) |
| Arachnoid cyst | 2 (0.0) | 0 |
| Arachnoiditis | 1 (0.0) | 0 |
| Ataxia | 0 | 1 (0.0) |
| Autoimmune encephalopathy | 0 | 1 (0.0) |
| Autonomic neuropathy | 1 (0.0) | 0 |
| Bell's palsy | 7 (0.1) | 10 (0.2) |
| Brachial plexopathy | 1 (0.0) | 0 |
| Brain injury | 2 (0.0) | 0 |
| Brain stem stroke | 1 (0.0) | 0 |
| Carotid arteriosclerosis | 1 (0.0) | 2 (0.0) |
| Carotid artery disease | 3 (0.1) | 2 (0.0) |
| Carotid artery dissection | 1 (0.0) | 0 |
| Carotid artery occlusion | 1 (0.0) | 0 |
| Carotid artery stenosis | 8 (0.2) | 5 (0.1) |
| Carpal tunnel syndrome | 76 (1.5) | 69 (1.4) |
| Central auditory processing disorder | 0 | 2 (0.0) |
| Cerebellar infarction | 0 | 1 (0.0) |
| Cerebellar stroke | 0 | 1 (0.0) |
| Cerebral atrophy | 1 (0.0) | 0 |
| Cerebral haemorrhage | 1 (0.0) | 0 |
| Cerebral ischaemia | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Cerebral thrombosis | 1 (0.0) | 0 |
| Cerebral venous thrombosis | 1 (0.0) | 0 |
| Cerebrovascular accident | 19 (0.4) | 20 (0.4) |
| Cervical radiculopathy | 7 (0.1) | 7 (0.1) |
| Cervicogenic headache | 0 | 1 (0.0) |
| Circadian rhythm sleep disorder | 1 (0.0) | 0 |
| Cluster headache | 2 (0.0) | 4 (0.1) |
| Cognitive disorder | 2 (0.0) | 1 (0.0) |
| Coma | 0 | 2 (0.0) |
| Cubital tunnel syndrome | 0 | 1 (0.0) |
| Dementia | 2 (0.0) | 2 (0.0) |
| Dementia Alzheimer's type | 0 | 1 (0.0) |
| Diabetic neuropathy | 35 (0.7) | 22 (0.4) |
| Disturbance in attention | 2 (0.0) | 1 (0.0) |
| Dizziness | 10 (0.2) | 10 (0.2) |
| Dizziness postural | 2 (0.0) | 0 |
| Drug withdrawal headache | 1 (0.0) | 0 |
| Dysgeusia | 0 | 1 (0.0) |
| Dyslexia | 1 (0.0) | 1 (0.0) |
| Dystonia | 0 | 2 (0.0) |
| Embolic stroke | 0 | 1 (0.0) |
| Epilepsy | 11 (0.2) | 12 (0.2) |
| Essential tremor | 8 (0.2) | 7 (0.1) |
| Extrapyramidal disorder | 0 | 1 (0.0) |
| Facial paralysis | 1 (0.0) | 0 |
| Generalised tonic-clonic seizure | 2 (0.0) | 1 (0.0) |
| Glossopharyngeal neuralgia | 1 (0.0) | 0 |
| Haemorrhagic stroke | 1 (0.0) | 1 (0.0) |
| Head titubation | 0 | 1 (0.0) |
| Headache | 163 (3.2) | 152 (3.0) |
| Hemiparesis | 1 (0.0) | 0 |
| Hemiplegia | 3 (0.1) | 0 |
| Hemiplegic migraine | 0 | 1 (0.0) |
| Horner's syndrome | 0 | 1 (0.0) |
| Hypersomnia | 1 (0.0) | 4 (0.1) |
| Hypoaesthesia | 4 (0.1) | 7 (0.1) |
| Hypogeusia | 1 (0.0) | 0 |
| Hyposmia | 2 (0.0) | 0 |
| Hypotonia | 0 | 1 (0.0) |
| Hypoxic-ischaemic encephalopathy | 0 | 1 (0.0) |
| IVth nerve paralysis | 1 (0.0) | 0 |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Idiopathic intracranial hypertension | 1 (0.0) | 1 (0.0) |
| Intention tremor | 1 (0.0) | 0 |
| Intracranial aneurysm | 2 (0.0) | 1 (0.0) |
| Intracranial pressure increased | 2 (0.0) | 1 (0.0) |
| Ischaemic stroke | 3 (0.1) | 1 (0.0) |
| Lacunar stroke | 0 | 1 (0.0) |
| Lethargy | 1 (0.0) | 0 |
| Lumbar radiculopathy | 17 (0.3) | 12 (0.2) |
| Medication overuse headache | 1 (0.0) | 0 |
| Memory impairment | 0 | 2 (0.0) |
| Migraine | 312 (6.1) | 287 (5.7) |
| Migraine with aura | 8 (0.2) | 7 (0.1) |
| Migraine without aura | 8 (0.2) | 8 (0.2) |
| Monoparesis | 0 | 1 (0.0) |
| Monoplegia | 1 (0.0) | 1 (0.0) |
| Morton's neuralgia | 3 (0.1) | 4 (0.1) |
| Multiple sclerosis | 1 (0.0) | 2 (0.0) |
| Muscle contractions involuntary | 2 (0.0) | 1 (0.0) |
| Muscle spasticity | 0 | 1 (0.0) |
| Myasthenia gravis | 0 | 1 (0.0) |
| Myelopathy | 0 | 1 (0.0) |
| Myoclonus | 1 (0.0) | 0 |
| Narcolepsy | 1 (0.0) | 4 (0.1) |
| Nerve compression | 10 (0.2) | 8 (0.2) |
| Nervous system disorder | 1 (0.0) | 0 |
| Neuralgia | 14 (0.3) | 15 (0.3) |
| Neuralgic amyotrophy | 0 | 1 (0.0) |
| Neuropathy peripheral | 67 (1.3) | 47 (0.9) |
| Nystagmus | 1 (0.0) | 2 (0.0) |
| Occipital neuralgia | 1 (0.0) | 1 (0.0) |
| Olfactory nerve disorder | 1 (0.0) | 0 |
| Ophthalmic migraine | 5 (0.1) | 3 (0.1) |
| Optic neuritis | 0 | 1 (0.0) |
| Paraesthesia | 5 (0.1) | 2 (0.0) |
| Paraparesis | 1 (0.0) | 0 |
| Parkinson's disease | 3 (0.1) | 5 (0.1) |
| Parkinsonism | 2 (0.0) | 0 |
| Partial seizures | 1 (0.0) | 0 |
| Periodic limb movement disorder | 0 | 2 (0.0) |
| Peripheral sensory neuropathy | 1 (0.0) | 1 (0.0) |
| Peroneal nerve palsy | 3 (0.1) | 3 (0.1) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Piriformis syndrome | 1 (0.0) | 0 |
| Polyneuropathy | 2 (0.0) | 3 (0.1) |
| Polyneuropathy alcoholic | 1 (0.0) | 0 |
| Post herpetic neuralgia | 1 (0.0) | 2 (0.0) |
| Post polio syndrome | 1 (0.0) | 1 (0.0) |
| Post-traumatic headache | 0 | 2 (0.0) |
| Post-traumatic neuralgia | 1 (0.0) | 0 |
| Presyncope | 0 | 2 (0.0) |
| Radial nerve compression | 0 | 1 (0.0) |
| Radicular pain | 1 (0.0) | 0 |
| Radiculitis brachial | 0 | 1 (0.0) |
| Radiculopathy | 0 | 3 (0.1) |
| Restless legs syndrome | 47 (0.9) | 49 (1.0) |
| Sciatic nerve neuropathy | 0 | 1 (0.0) |
| Sciatica | 44 (0.9) | 45 (0.9) |
| Seizure | 15 (0.3) | 20 (0.4) |
| Senile dementia | 0 | 1 (0.0) |
| Serotonin syndrome | 0 | 1 (0.0) |
| Shift work disorder | 1 (0.0) | 1 (0.0) |
| Sinus headache | 13 (0.3) | 12 (0.2) |
| Sleep deficit | 1 (0.0) | 0 |
| Small fibre neuropathy | 1 (0.0) | 0 |
| Somnolence | 1 (0.0) | 1 (0.0) |
| Spasmodic dysphonia | 2 (0.0) | 1 (0.0) |
| Spinal cord disorder | 1 (0.0) | 0 |
| Spinal meningeal cyst | 0 | 1 (0.0) |
| Subarachnoid haemorrhage | 4 (0.1) | 2 (0.0) |
| Syncope | 6 (0.1) | 17 (0.3) |
| Tarsal tunnel syndrome | 1 (0.0) | 1 (0.0) |
| Temporal lobe epilepsy | 1 (0.0) | 0 |
| Tension headache | 38 (0.7) | 30 (0.6) |
| Thoracic outlet syndrome | 1 (0.0) | 1 (0.0) |
| Thoracic radiculopathy | 1 (0.0) | 0 |
| Transient ischaemic attack | 19 (0.4) | 15 (0.3) |
| Tremor | 9 (0.2) | 12 (0.2) |
| Trigeminal nerve disorder | 0 | 2 (0.0) |
| Trigeminal neuralgia | 3 (0.1) | 5 (0.1) |
| Ulnar tunnel syndrome | 0 | 1 (0.0) |
| Vertebral artery dissection | 0 | 1 (0.0) |
| Vocal cord paralysis | 1 (0.0) | 3 (0.1) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Pregnancy, puerperium and perinatal conditions | 43 (0.8) | 36 (0.7) |
| Abnormal cord insertion | 0 | 1 (0.0) |
| Abortion spontaneous | 8 (0.2) | 9 (0.2) |
| Cephalo-pelvic disproportion | 1 (0.0) | 0 |
| Complication of pregnancy | 0 | 1 (0.0) |
| Delivery | 18 (0.4) | 13 (0.3) |
| Eclampsia | 0 | 1 (0.0) |
| Ectopic pregnancy | 5 (0.1) | 5 (0.1) |
| Gestational diabetes | 4 (0.1) | 3 (0.1) |
| Habitual abortion | 0 | 1 (0.0) |
| Peripartum cardiomyopathy | 1 (0.0) | 0 |
| Placenta accreta | 1 (0.0) | 0 |
| Postpartum haemorrhage | 1 (0.0) | 1 (0.0) |
| Pre-eclampsia | 2 (0.0) | 1 (0.0) |
| Pregnancy | 2 (0.0) | 2 (0.0) |
| Premature baby | 1 (0.0) | 0 |
| Premature labour | 1 (0.0) | 0 |
| Stillbirth | 0 | 1 (0.0) |
| Product issues | 0 | 1 (0.0) |
| Device dislocation | 0 | 1 (0.0) |
| Psychiatric disorders | 1335 (26.3) | 1330 (26.4) |
| Adjustment disorder | 1 (0.0) | 4 (0.1) |
| Adjustment disorder with depressed mood | 4 (0.1) | 6 (0.1) |
| Adjustment disorder with mixed anxiety and depressed mood | 1 (0.0) | 1 (0.0) |
| Aerophobia | 1 (0.0) | 0 |
| Affect lability | 0 | 2 (0.0) |
| Affective disorder | 2 (0.0) | 4 (0.1) |
| Agitation | 1 (0.0) | 0 |
| Agoraphobia | 0 | 1 (0.0) |
| Alcohol abuse | 4 (0.1) | 3 (0.1) |
| Alcohol use disorder | 1 (0.0) | 2 (0.0) |
| Alcoholism | 5 (0.1) | 15 (0.3) |
| Anorexia nervosa | 1 (0.0) | 1 (0.0) |
| Anxiety | 549 (10.8) | 553 (11.0) |
| Anxiety disorder | 26 (0.5) | 33 (0.7) |
| Attention deficit hyperactivity disorder | 155 (3.1) | 163 (3.2) |
| Autism spectrum disorder | 3 (0.1) | 3 (0.1) |
| Binge eating | 3 (0.1) | 2 (0.0) |
| Bipolar I disorder | 0 | 2 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Bipolar II disorder | 4 (0.1) | 4 (0.1) |
| Bipolar disorder | 39 (0.8) | 23 (0.5) |
| Borderline personality disorder | 0 | 1 (0.0) |
| Breathing-related sleep disorder | 1 (0.0) | 0 |
| Bulimia nervosa | 0 | 1 (0.0) |
| Conversion disorder | 0 | 1 (0.0) |
| Cyclothymic disorder | 0 | 1 (0.0) |
| Delirium | 1 (0.0) | 0 |
| Depressed mood | 0 | 2 (0.0) |
| Depression | 575 (11.3) | 557 (11.0) |
| Depression suicidal | 1 (0.0) | 0 |
| Drug abuse | 4 (0.1) | 6 (0.1) |
| Drug dependence | 4 (0.1) | 1 (0.0) |
| Eating disorder | 1 (0.0) | 4 (0.1) |
| Encopresis | 1 (0.0) | 0 |
| Enuresis | 2 (0.0) | 0 |
| Gender dysphoria | 1 (0.0) | 1 (0.0) |
| Generalised anxiety disorder | 37 (0.7) | 28 (0.6) |
| Grief reaction | 1 (0.0) | 1 (0.0) |
| Hallucination | 1 (0.0) | 0 |
| Impulse-control disorder | 0 | 1 (0.0) |
| Initial insomnia | 1 (0.0) | 0 |
| Insomnia | 365 (7.2) | 309 (6.1) |
| Libido decreased | 14 (0.3) | 14 (0.3) |
| Major depression | 51 (1.0) | 43 (0.9) |
| Mental disorder | 0 | 2 (0.0) |
| Mental status changes | 1 (0.0) | 0 |
| Middle insomnia | 1 (0.0) | 0 |
| Mixed anxiety and depressive disorder | 0 | 1 (0.0) |
| Mood swings | 0 | 3 (0.1) |
| Nicotine dependence | 15 (0.3) | 11 (0.2) |
| Obsessive-compulsive disorder | 8 (0.2) | 17 (0.3) |
| Panic attack | 5 (0.1) | 8 (0.2) |
| Panic disorder | 4 (0.1) | 6 (0.1) |
| Panic reaction | 1 (0.0) | 0 |
| Performance fear | 2 (0.0) | 0 |
| Perinatal depression | 5 (0.1) | 6 (0.1) |
| Persistent depressive disorder | 0 | 1 (0.0) |
| Post-traumatic stress disorder | 35 (0.7) | 33 (0.7) |
| Postpartum anxiety | 2 (0.0) | 0 |
| Premature ejaculation | 1 (0.0) | 2 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Psychogenic erectile dysfunction | 0 | 1 (0.0) |
| Psychotic disorder | 1 (0.0) | 0 |
| Rapid eye movements sleep abnormal | 0 | 1 (0.0) |
| Restlessness | 0 | 1 (0.0) |
| Schizoaffective disorder | 0 | 1 (0.0) |
| Schizophrenia | 5 (0.1) | 4 (0.1) |
| Seasonal affective disorder | 10 (0.2) | 5 (0.1) |
| Sleep disorder | 5 (0.1) | 7 (0.1) |
| Sleep disorder due to general medical condition, insomnia type | 0 | 1 (0.0) |
| Sleep terror | 1 (0.0) | 0 |
| Social anxiety disorder | 4 (0.1) | 3 (0.1) |
| Somatic symptom disorder | 0 | 1 (0.0) |
| Stress | 3 (0.1) | 1 (0.0) |
| Substance abuse | 0 | 1 (0.0) |
| Substance dependence | 1 (0.0) | 0 |
| Suicidal ideation | 1 (0.0) | 0 |
| Suicide attempt | 3 (0.1) | 0 |
| Tobacco abuse | 3 (0.1) | 3 (0.1) |
| Trichotillomania | 0 | 1 (0.0) |
| Renal and urinary disorders | 343 (6.8) | 299 (5.9) |
| Acute kidney injury | 1 (0.0) | 2 (0.0) |
| Albuminuria | 1 (0.0) | 0 |
| Bladder disorder | 1 (0.0) | 0 |
| Bladder diverticulum | 1 (0.0) | 0 |
| Bladder neck obstruction | 1 (0.0) | 0 |
| Bladder obstruction | 1 (0.0) | 0 |
| Bladder outlet obstruction | 1 (0.0) | 0 |
| Bladder perforation | 1 (0.0) | 0 |
| Bladder prolapse | 10 (0.2) | 10 (0.2) |
| Bladder spasm | 1 (0.0) | 1 (0.0) |
| Bladder stenosis | 2 (0.0) | 0 |
| Chronic kidney disease | 27 (0.5) | 30 (0.6) |
| Cystitis interstitial | 6 (0.1) | 3 (0.1) |
| Diabetic nephropathy | 3 (0.1) | 3 (0.1) |
| Dysuria | 1 (0.0) | 2 (0.0) |
| Glomerulonephritis membranous | 0 | 1 (0.0) |
| Haematuria | 2 (0.0) | 4 (0.1) |
| Hydronephrosis | 1 (0.0) | 2 (0.0) |
| Hypercalciuria | 0 | 1 (0.0) |
| Hypertonic bladder | 54 (1.1) | 53 (1.1) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| IgA nephropathy | 1 (0.0) | 0 |
| Incontinence | 4 (0.1) | 3 (0.1) |
| Lower urinary tract symptoms | 3 (0.1) | 0 |
| Lupus nephritis | 1 (0.0) | 0 |
| Microalbuminuria | 3 (0.1) | 1 (0.0) |
| Micturition disorder | 3 (0.1) | 2 (0.0) |
| Micturition urgency | 4 (0.1) | 4 (0.1) |
| Mixed incontinence | 2 (0.0) | 1 (0.0) |
| Nephrolithiasis | 136 (2.7) | 121 (2.4) |
| Nephropathy | 3 (0.1) | 5 (0.1) |
| Nocturia | 16 (0.3) | 6 (0.1) |
| Pollakiuria | 6 (0.1) | 7 (0.1) |
| Polyuria | 2 (0.0) | 1 (0.0) |
| Post streptococcal glomerulonephritis | 0 | 1 (0.0) |
| Proteinuria | 3 (0.1) | 0 |
| Reflux nephropathy | 0 | 1 (0.0) |
| Renal colic | 1 (0.0) | 0 |
| Renal cyst | 4 (0.1) | 4 (0.1) |
| Renal disorder | 1 (0.0) | 3 (0.1) |
| Renal failure | 1 (0.0) | 3 (0.1) |
| Renal impairment | 1 (0.0) | 2 (0.0) |
| Renal infarct | 0 | 1 (0.0) |
| Renal mass | 1 (0.0) | 0 |
| Single functional kidney | 1 (0.0) | 1 (0.0) |
| Stress urinary incontinence | 20 (0.4) | 8 (0.2) |
| Ureteric stenosis | 1 (0.0) | 1 (0.0) |
| Ureterolithiasis | 0 | 2 (0.0) |
| Urethral cyst | 1 (0.0) | 0 |
| Urethral pain | 1 (0.0) | 0 |
| Urethral stenosis | 1 (0.0) | 2 (0.0) |
| Urge incontinence | 8 (0.2) | 6 (0.1) |
| Urinary hesitation | 0 | 2 (0.0) |
| Urinary incontinence | 32 (0.6) | 28 (0.6) |
| Urinary retention | 6 (0.1) | 7 (0.1) |
| Urine flow decreased | 1 (0.0) | 0 |
| Urogenital fistula | 0 | 1 (0.0) |
| Reproductive system and breast disorders | 662 (13.0) | 672 (13.3) |
| Abnormal uterine bleeding | 12 (0.2) | 8 (0.2) |
| Adenomyosis | 3 (0.1) | 6 (0.1) |
| Adnexa uteri cyst | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Adnexa uteri pain | 0 | 1 (0.0) |
| Adnexal torsion | 1 (0.0) | 1 (0.0) |
| Amenorrhoea | 5 (0.1) | 7 (0.1) |
| Anisomastia | 1 (0.0) | 0 |
| Artificial menopause | 1 (0.0) | 0 |
| Atrophic vulvovaginitis | 2 (0.0) | 6 (0.1) |
| Azoospermia | 1 (0.0) | 0 |
| Balanoposthitis | 1 (0.0) | 0 |
| Bartholin's cyst | 2 (0.0) | 1 (0.0) |
| Benign prostatic hyperplasia | 152 (3.0) | 158 (3.1) |
| Breast calcifications | 1 (0.0) | 3 (0.1) |
| Breast cyst | 7 (0.1) | 7 (0.1) |
| Breast disorder | 1 (0.0) | 0 |
| Breast enlargement | 2 (0.0) | 4 (0.1) |
| Breast fibrosis | 0 | 1 (0.0) |
| Breast hyperplasia | 0 | 1 (0.0) |
| Breast mass | 8 (0.2) | 5 (0.1) |
| Breast pain | 1 (0.0) | 0 |
| Breast swelling | 1 (0.0) | 0 |
| Cervical dysplasia | 6 (0.1) | 4 (0.1) |
| Cervical polyp | 1 (0.0) | 1 (0.0) |
| Cervix disorder | 1 (0.0) | 0 |
| Cervix haemorrhage uterine | 1 (0.0) | 0 |
| Colpocele | 1 (0.0) | 0 |
| Cystocele | 4 (0.1) | 3 (0.1) |
| Dysmenorrhoea | 22 (0.4) | 22 (0.4) |
| Dyspareunia | 4 (0.1) | 3 (0.1) |
| Endometrial hyperplasia | 2 (0.0) | 2 (0.0) |
| Endometrial thickening | 0 | 1 (0.0) |
| Endometriosis | 71 (1.4) | 71 (1.4) |
| Epididymal cyst | 0 | 1 (0.0) |
| Epididymal tenderness | 0 | 1 (0.0) |
| Erectile dysfunction | 93 (1.8) | 109 (2.2) |
| Fallopian tube obstruction | 0 | 3 (0.1) |
| Female genital tract fistula | 1 (0.0) | 0 |
| Fibrocystic breast disease | 13 (0.3) | 6 (0.1) |
| Genital haemorrhage | 1 (0.0) | 0 |
| Genital lesion | 1 (0.0) | 0 |
| Gynaecomastia | 2 (0.0) | 2 (0.0) |
| Haematospermia | 0 | 1 (0.0) |
| Heavy menstrual bleeding | 70 (1.4) | 57 (1.1) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Infertility | 4 (0.1) | 9 (0.2) |
| Infertility female | 1 (0.0) | 2 (0.0) |
| Intermenstrual bleeding | 1 (0.0) | 2 (0.0) |
| Lactation puerperal increased | 1 (0.0) | 0 |
| Menometrorrhagia | 2 (0.0) | 0 |
| Menopausal symptoms | 21 (0.4) | 17 (0.3) |
| Menstrual disorder | 7 (0.1) | 5 (0.1) |
| Menstruation irregular | 10 (0.2) | 9 (0.2) |
| Oligomenorrhoea | 2 (0.0) | 2 (0.0) |
| Oligospermia | 1 (0.0) | 0 |
| Organic erectile dysfunction | 1 (0.0) | 0 |
| Ovarian adhesion | 1 (0.0) | 0 |
| Ovarian cyst | 35 (0.7) | 49 (1.0) |
| Ovarian cyst ruptured | 1 (0.0) | 5 (0.1) |
| Ovarian fibrosis | 0 | 1 (0.0) |
| Ovarian haemorrhage | 1 (0.0) | 0 |
| Ovarian mass | 1 (0.0) | 0 |
| Ovarian rupture | 0 | 1 (0.0) |
| Ovulation pain | 1 (0.0) | 1 (0.0) |
| Pelvic cyst | 0 | 1 (0.0) |
| Pelvic organ prolapse | 2 (0.0) | 1 (0.0) |
| Pelvic pain | 5 (0.1) | 5 (0.1) |
| Polycystic ovaries | 25 (0.5) | 50 (1.0) |
| Postmenopausal haemorrhage | 2 (0.0) | 2 (0.0) |
| Premature menopause | 7 (0.1) | 1 (0.0) |
| Premenstrual dysphoric disorder | 1 (0.0) | 1 (0.0) |
| Premenstrual syndrome | 1 (0.0) | 3 (0.1) |
| Prostatic disorder | 1 (0.0) | 3 (0.1) |
| Prostatic dysplasia | 0 | 1 (0.0) |
| Prostatic mass | 0 | 1 (0.0) |
| Prostatism | 7 (0.1) | 1 (0.0) |
| Prostatitis | 5 (0.1) | 5 (0.1) |
| Prostatomegaly | 41 (0.8) | 37 (0.7) |
| Rectocele | 4 (0.1) | 3 (0.1) |
| Scrotal cyst | 1 (0.0) | 0 |
| Scrotal haemorrhage | 0 | 1 (0.0) |
| Sexual dysfunction | 2 (0.0) | 0 |
| Spermatocele | 1 (0.0) | 1 (0.0) |
| Testicular atrophy | 0 | 1 (0.0) |
| Testicular disorder | 1 (0.0) | 1 (0.0) |
| Testicular mass | 1 (0.0) | 1 (0.0) |

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| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Testicular pain | 0 | 1 (0.0) |
| Testicular torsion | 0 | 1 (0.0) |
| Uterine cyst | 2 (0.0) | 0 |
| Uterine disorder | 1 (0.0) | 0 |
| Uterine haemorrhage | 1 (0.0) | 4 (0.1) |
| Uterine malposition | 1 (0.0) | 0 |
| Uterine polyp | 6 (0.1) | 3 (0.1) |
| Uterine prolapse | 10 (0.2) | 16 (0.3) |
| Uterine scar | 0 | 2 (0.0) |
| Vaginal discharge | 1 (0.0) | 0 |
| Vaginal haemorrhage | 5 (0.1) | 5 (0.1) |
| Vaginal polyp | 0 | 1 (0.0) |
| Vaginal prolapse | 2 (0.0) | 0 |
| Vaginal stricture | 1 (0.0) | 0 |
| Varicocele | 4 (0.1) | 3 (0.1) |
| Vulval disorder | 1 (0.0) | 1 (0.0) |
| Vulvovaginal dryness | 10 (0.2) | 6 (0.1) |
| Vulvovaginal pain | 1 (0.0) | 0 |
| Respiratory, thoracic and mediastinal disorders | 963 (19.0) | 995 (19.7) |
| Adenoidal hypertrophy | 3 (0.1) | 6 (0.1) |
| Allergic bronchitis | 1 (0.0) | 2 (0.0) |
| Allergic cough | 1 (0.0) | 2 (0.0) |
| Allergic pharyngitis | 0 | 1 (0.0) |
| Allergic sinusitis | 13 (0.3) | 9 (0.2) |
| Apnoea | 0 | 1 (0.0) |
| Asthma | 354 (7.0) | 397 (7.9) |
| Asthma exercise induced | 23 (0.5) | 19 (0.4) |
| Bronchial hyperreactivity | 8 (0.2) | 9 (0.2) |
| Bronchiectasis | 2 (0.0) | 0 |
| Bronchitis chronic | 9 (0.2) | 5 (0.1) |
| Bronchospasm | 3 (0.1) | 2 (0.0) |
| Childhood asthma | 4 (0.1) | 3 (0.1) |
| Chronic obstructive pulmonary disease | 55 (1.1) | 58 (1.1) |
| Chronic respiratory disease | 0 | 1 (0.0) |
| Cough | 8 (0.2) | 15 (0.3) |
| Cough variant asthma | 0 | 1 (0.0) |
| Cystic lung disease | 2 (0.0) | 0 |
| Diaphragmatic paralysis | 1 (0.0) | 0 |
| Dyspnoea | 5 (0.1) | 12 (0.2) |
| Dyspnoea exertional | 1 (0.0) | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Emphysema | 5 (0.1) | 12 (0.2) |
| Epiglottic oedema | 0 | 1 (0.0) |
| Epistaxis | 5 (0.1) | 4 (0.1) |
| Haemoptysis | 0 | 1 (0.0) |
| Hypoxia | 1 (0.0) | 3 (0.1) |
| Nasal congestion | 5 (0.1) | 3 (0.1) |
| Nasal discomfort | 2 (0.0) | 0 |
| Nasal disorder | 1 (0.0) | 0 |
| Nasal obstruction | 1 (0.0) | 0 |
| Nasal polyps | 8 (0.2) | 7 (0.1) |
| Nasal septum deviation | 56 (1.1) | 58 (1.1) |
| Nasal turbinate hypertrophy | 0 | 3 (0.1) |
| Organising pneumonia | 0 | 1 (0.0) |
| Oropharyngeal pain | 4 (0.1) | 6 (0.1) |
| Paranasal cyst | 0 | 1 (0.0) |
| Pharyngeal polyp | 1 (0.0) | 0 |
| Pleural calcification | 0 | 1 (0.0) |
| Pleurisy | 2 (0.0) | 1 (0.0) |
| Pneumothorax | 4 (0.1) | 5 (0.1) |
| Pneumothorax spontaneous | 3 (0.1) | 1 (0.0) |
| Productive cough | 0 | 1 (0.0) |
| Pulmonary calcification | 1 (0.0) | 0 |
| Pulmonary embolism | 15 (0.3) | 13 (0.3) |
| Pulmonary granuloma | 2 (0.0) | 2 (0.0) |
| Pulmonary hypertension | 2 (0.0) | 2 (0.0) |
| Pulmonary mass | 7 (0.1) | 12 (0.2) |
| Pulmonary oedema | 1 (0.0) | 0 |
| Pulmonary thrombosis | 1 (0.0) | 0 |
| Reflux laryngitis | 3 (0.1) | 1 (0.0) |
| Respiratory tract congestion | 0 | 1 (0.0) |
| Restrictive pulmonary disease | 1 (0.0) | 1 (0.0) |
| Rhinitis allergic | 286 (5.6) | 261 (5.2) |
| Rhinitis perennial | 12 (0.2) | 17 (0.3) |
| Rhinorrhoea | 1 (0.0) | 3 (0.1) |
| Sinus congestion | 4 (0.1) | 6 (0.1) |
| Sinus disorder | 1 (0.0) | 5 (0.1) |
| Sinus polyp | 2 (0.0) | 6 (0.1) |
| Sleep apnoea syndrome | 187 (3.7) | 207 (4.1) |
| Snoring | 1 (0.0) | 1 (0.0) |
| Tonsillar disorder | 0 | 1 (0.0) |
| Tonsillar hypertrophy | 6 (0.1) | 6 (0.1) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Tonsillar inflammation | 1 (0.0) | 1 (0.0) |
| Tonsillolith | 1 (0.0) | 2 (0.0) |
| Upper-airway cough syndrome | 5 (0.1) | 7 (0.1) |
| Vasomotor rhinitis | 1 (0.0) | 1 (0.0) |
| Vocal cord polyp | 3 (0.1) | 1 (0.0) |
| Vocal cord thickening | 0 | 1 (0.0) |
| Wheezing | 2 (0.0) | 0 |
| Skin and subcutaneous tissue disorders | 505 (9.9) | 525 (10.4) |
| Acne | 117 (2.3) | 100 (2.0) |
| Acne cystic | 2 (0.0) | 0 |
| Actinic keratosis | 27 (0.5) | 37 (0.7) |
| Alopecia | 32 (0.6) | 31 (0.6) |
| Alopecia areata | 3 (0.1) | 1 (0.0) |
| Androgenetic alopecia | 5 (0.1) | 3 (0.1) |
| Brow ptosis | 0 | 1 (0.0) |
| Cafe au lait spots | 1 (0.0) | 0 |
| Chloasma | 1 (0.0) | 0 |
| Chronic spontaneous urticaria | 2 (0.0) | 0 |
| Cutaneous lupus erythematosus | 0 | 1 (0.0) |
| Dandruff | 1 (0.0) | 2 (0.0) |
| Decubitus ulcer | 1 (0.0) | 0 |
| Dermal cyst | 10 (0.2) | 5 (0.1) |
| Dermatitis | 12 (0.2) | 14 (0.3) |
| Dermatitis allergic | 2 (0.0) | 2 (0.0) |
| Dermatitis atopic | 14 (0.3) | 19 (0.4) |
| Dermatitis contact | 35 (0.7) | 25 (0.5) |
| Dermatomyositis | 1 (0.0) | 0 |
| Dermatosis | 1 (0.0) | 0 |
| Diffuse alopecia | 0 | 1 (0.0) |
| Drug eruption | 19 (0.4) | 10 (0.2) |
| Dry skin | 6 (0.1) | 4 (0.1) |
| Dyshidrotic eczema | 1 (0.0) | 2 (0.0) |
| Eczema | 81 (1.6) | 84 (1.7) |
| Eczema nummular | 0 | 1 (0.0) |
| Eosinophilic cellulitis | 0 | 1 (0.0) |
| Erythema | 2 (0.0) | 0 |
| Granuloma annulare | 3 (0.1) | 2 (0.0) |
| Granuloma skin | 1 (0.0) | 0 |
| Hair growth abnormal | 0 | 1 (0.0) |
| Hand dermatitis | 7 (0.1) | 9 (0.2) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Henoch-Schonlein purpura | 0 | 1 (0.0) |
| Hidradenitis | 3 (0.1) | 3 (0.1) |
| Hirsutism | 2 (0.0) | 4 (0.1) |
| Hyperhidrosis | 6 (0.1) | 3 (0.1) |
| Hyperkeratosis | 2 (0.0) | 0 |
| Idiopathic guttate hypomelanosis | 0 | 1 (0.0) |
| Idiopathic urticaria | 2 (0.0) | 1 (0.0) |
| Ingrowing nail | 1 (0.0) | 3 (0.1) |
| Intertrigo | 1 (0.0) | 1 (0.0) |
| Keloid scar | 1 (0.0) | 1 (0.0) |
| Keratosis pilaris | 3 (0.1) | 3 (0.1) |
| Lentigo | 1 (0.0) | 1 (0.0) |
| Lichen planopilaris | 1 (0.0) | 1 (0.0) |
| Lichen planus | 3 (0.1) | 3 (0.1) |
| Lichen sclerosus | 1 (0.0) | 1 (0.0) |
| Lichenification | 0 | 1 (0.0) |
| Mechanical urticaria | 0 | 3 (0.1) |
| Miliaria | 0 | 1 (0.0) |
| Nail dystrophy | 0 | 1 (0.0) |
| Necrobiosis lipoidica diabeticorum | 1 (0.0) | 0 |
| Neurodermatitis | 1 (0.0) | 3 (0.1) |
| Night sweats | 1 (0.0) | 0 |
| Onychomadesis | 1 (0.0) | 0 |
| Papulopustular rosacea | 1 (0.0) | 0 |
| Photodermatosis | 0 | 1 (0.0) |
| Pityriasis rosea | 1 (0.0) | 0 |
| Polymorphic light eruption | 1 (0.0) | 0 |
| Precancerous skin lesion | 0 | 2 (0.0) |
| Pruritus | 7 (0.1) | 4 (0.1) |
| Pruritus allergic | 2 (0.0) | 1 (0.0) |
| Pseudofolliculitis | 1 (0.0) | 0 |
| Psoriasis | 35 (0.7) | 46 (0.9) |
| Punctate keratosis | 1 (0.0) | 0 |
| Purpura | 1 (0.0) | 0 |
| Purpura senile | 1 (0.0) | 1 (0.0) |
| Rash | 12 (0.2) | 14 (0.3) |
| Rash macular | 1 (0.0) | 0 |
| Rosacea | 48 (0.9) | 66 (1.3) |
| Seborrhoea | 1 (0.0) | 1 (0.0) |
| Seborrhoeic dermatitis | 14 (0.3) | 15 (0.3) |
| Sensitive skin | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Skin atrophy | 0 | 1 (0.0) |
| Skin burning sensation | 0 | 1 (0.0) |
| Skin discolouration | 1 (0.0) | 3 (0.1) |
| Skin exfoliation | 1 (0.0) | 0 |
| Skin hypertrophy | 0 | 1 (0.0) |
| Skin hypopigmentation | 0 | 1 (0.0) |
| Skin irritation | 1 (0.0) | 0 |
| Skin lesion | 1 (0.0) | 3 (0.1) |
| Skin ulcer | 1 (0.0) | 1 (0.0) |
| Solar lentigo | 0 | 1 (0.0) |
| Stevens-Johnson syndrome | 1 (0.0) | 0 |
| Transient acantholytic dermatosis | 2 (0.0) | 1 (0.0) |
| Urticaria | 16 (0.3) | 25 (0.5) |
| Vitiligo | 7 (0.1) | 4 (0.1) |
| Social circumstances | 906 (17.8) | 899 (17.8) |
| Alcohol use | 11 (0.2) | 14 (0.3) |
| Bereavement | 1 (0.0) | 1 (0.0) |
| Blood donor | 9 (0.2) | 10 (0.2) |
| Cardiac assistance device user | 1 (0.0) | 0 |
| Corrective lens user | 61 (1.2) | 67 (1.3) |
| Denture wearer | 0 | 2 (0.0) |
| Dependence on oxygen therapy | 0 | 1 (0.0) |
| Electronic cigarette user | 0 | 2 (0.0) |
| Ex-tobacco user | 26 (0.5) | 27 (0.5) |
| Familial risk factor | 2 (0.0) | 2 (0.0) |
| Hearing aid user | 5 (0.1) | 13 (0.3) |
| High risk sexual behaviour | 0 | 1 (0.0) |
| Menopause | 162 (3.2) | 157 (3.1) |
| Organ donor | 1 (0.0) | 3 (0.1) |
| Postmenopause | 620 (12.2) | 590 (11.7) |
| Social alcohol drinker | 4 (0.1) | 2 (0.0) |
| Substance use | 3 (0.1) | 9 (0.2) |
| Tobacco user | 53 (1.0) | 65 (1.3) |
| Trans-sexualism | 2 (0.0) | 1 (0.0) |
| Surgical and medical procedures | 2456 (48.3) | 2369 (47.0) |
| Abdominal hernia repair | 11 (0.2) | 17 (0.3) |
| Abdominal operation | 5 (0.1) | 0 |
| Abdominal panniculectomy | 1 (0.0) | 3 (0.1) |
| Abdominal wall operation | 1 (0.0) | 0 |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Abdominoplasty | 18 (0.4) | 23 (0.5) |
| Abortion induced | 0 | 1 (0.0) |
| Abscess drainage | 4 (0.1) | 2 (0.0) |
| Acoustic neuroma removal | 2 (0.0) | 0 |
| Adenoidectomy | 36 (0.7) | 36 (0.7) |
| Adenotonsillectomy | 6 (0.1) | 8 (0.2) |
| Adhesiolysis | 1 (0.0) | 0 |
| Adrenalectomy | 1 (0.0) | 2 (0.0) |
| Alcohol rehabilitation | 1 (0.0) | 1 (0.0) |
| Amblyopia therapy | 1 (0.0) | 0 |
| Aneurysm repair | 1 (0.0) | 0 |
| Angioplasty | 2 (0.0) | 2 (0.0) |
| Ankle arthroplasty | 5 (0.1) | 3 (0.1) |
| Ankle operation | 10 (0.2) | 26 (0.5) |
| Anorectal operation | 4 (0.1) | 0 |
| Antibiotic prophylaxis | 3 (0.1) | 1 (0.0) |
| Antibiotic therapy | 1 (0.0) | 0 |
| Anticoagulant therapy | 1 (0.0) | 0 |
| Antidepressant therapy | 1 (0.0) | 0 |
| Anxiolytic therapy | 2 (0.0) | 0 |
| Aorta coarctation repair | 0 | 1 (0.0) |
| Aortic aneurysm repair | 5 (0.1) | 1 (0.0) |
| Aortic stent insertion | 1 (0.0) | 0 |
| Aortic surgery | 1 (0.0) | 2 (0.0) |
| Aortic valve repair | 1 (0.0) | 1 (0.0) |
| Aortic valve replacement | 3 (0.1) | 6 (0.1) |
| Apicectomy | 1 (0.0) | 0 |
| Appendicectomy | 207 (4.1) | 192 (3.8) |
| Arm amputation | 0 | 1 (0.0) |
| Arterial repair | 1 (0.0) | 1 (0.0) |
| Arterial stent insertion | 1 (0.0) | 0 |
| Arterial therapeutic procedure | 1 (0.0) | 0 |
| Arteriovenous fistula operation | 0 | 1 (0.0) |
| Arthrodesis | 9 (0.2) | 6 (0.1) |
| Arthroscopic surgery | 2 (0.0) | 0 |
| Artificial crown procedure | 2 (0.0) | 1 (0.0) |
| Artificial insemination | 0 | 1 (0.0) |
| Artificial urinary sphincter implant | 1 (0.0) | 0 |
| Astrocytoma surgery | 1 (0.0) | 0 |
| Atrial septal defect repair | 4 (0.1) | 5 (0.1) |
| Axillary lymphadenectomy | 1 (0.0) | 0 |

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|---|---|---|
| Bartholin's cyst removal | 1 (0.0) | 1 (0.0) |
| Benign breast lump removal | 6 (0.1) | 10 (0.2) |
| Benign tumour excision | 2 (0.0) | 1 (0.0) |
| Bilateral orchidectomy | 1 (0.0) | 2 (0.0) |
| Birth defect correction | 1 (0.0) | 0 |
| Bladder ablation | 1 (0.0) | 0 |
| Bladder lesion excision | 2 (0.0) | 0 |
| Bladder neck operation | 1 (0.0) | 0 |
| Bladder neoplasm surgery | 4 (0.1) | 0 |
| Bladder operation | 1 (0.0) | 5 (0.1) |
| Bladder repair | 3 (0.1) | 3 (0.1) |
| Blepharoplasty | 12 (0.2) | 7 (0.1) |
| Blood donation | 1 (0.0) | 0 |
| Bone cyst excision | 2 (0.0) | 0 |
| Bone debridement | 1 (0.0) | 0 |
| Bone graft | 2 (0.0) | 1 (0.0) |
| Bone lesion excision | 7 (0.1) | 15 (0.3) |
| Bone operation | 29 (0.6) | 15 (0.3) |
| Bone prosthesis insertion | 1 (0.0) | 0 |
| Botulinum toxin injection | 1 (0.0) | 1 (0.0) |
| Brachytherapy | 2 (0.0) | 0 |
| Brachytherapy to prostate | 2 (0.0) | 0 |
| Brain operation | 1 (0.0) | 0 |
| Brain stent insertion | 1 (0.0) | 0 |
| Brain tumour operation | 1 (0.0) | 2 (0.0) |
| Breast conserving surgery | 36 (0.7) | 41 (0.8) |
| Breast cyst excision | 2 (0.0) | 4 (0.1) |
| Breast operation | 1 (0.0) | 3 (0.1) |
| Breast prosthesis removal | 3 (0.1) | 4 (0.1) |
| Breast reconstruction | 5 (0.1) | 2 (0.0) |
| Breast tumour excision | 0 | 2 (0.0) |
| Bunion operation | 35 (0.7) | 36 (0.7) |
| Bursa removal | 1 (0.0) | 0 |
| CSF shunt operation | 1 (0.0) | 0 |
| Caecectomy | 1 (0.0) | 0 |
| Caecopexy | 1 (0.0) | 0 |
| Caesarean section | 165 (3.2) | 169 (3.4) |
| Calcific deposits removal | 0 | 1 (0.0) |
| Cancer surgery | 27 (0.5) | 21 (0.4) |
| Capsulorrhaphy | 1 (0.0) | 0 |
| Cardiac ablation | 24 (0.5) | 15 (0.3) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Cardiac operation | 3 (0.1) | 6 (0.1) |
| Cardiac pacemaker insertion | 24 (0.5) | 10 (0.2) |
| Cardiac pacemaker replacement | 1 (0.0) | 0 |
| Cardiac resynchronisation therapy | 1 (0.0) | 0 |
| Cardioversion | 4 (0.1) | 2 (0.0) |
| Carotid artery stent insertion | 1 (0.0) | 3 (0.1) |
| Carotid endarterectomy | 4 (0.1) | 1 (0.0) |
| Carotid revascularisation | 1 (0.0) | 0 |
| Carpal tunnel decompression | 45 (0.9) | 46 (0.9) |
| Carpectomy | 1 (0.0) | 0 |
| Cartilage graft | 1 (0.0) | 0 |
| Cartilage operation | 1 (0.0) | 0 |
| Cataract operation | 140 (2.8) | 106 (2.1) |
| Cautery to nose | 0 | 2 (0.0) |
| Central venous catheter removal | 2 (0.0) | 0 |
| Central venous catheterisation | 4 (0.1) | 1 (0.0) |
| Cervical conisation | 1 (0.0) | 0 |
| Cervix cryotherapy | 0 | 3 (0.1) |
| Cheilectomy | 1 (0.0) | 2 (0.0) |
| Chemotherapy | 2 (0.0) | 6 (0.1) |
| Chest tube insertion | 0 | 1 (0.0) |
| Cholecystectomy | 255 (5.0) | 233 (4.6) |
| Cholelithotomy | 0 | 3 (0.1) |
| Chondrectomy | 0 | 1 (0.0) |
| Chondroplasty | 18 (0.4) | 12 (0.2) |
| Circumcision | 5 (0.1) | 7 (0.1) |
| Cleft lip repair | 0 | 1 (0.0) |
| Cleft palate repair | 3 (0.1) | 0 |
| Coccygectomy | 1 (0.0) | 1 (0.0) |
| Cochlea implant | 3 (0.1) | 2 (0.0) |
| Colectomy | 16 (0.3) | 14 (0.3) |
| Colectomy total | 1 (0.0) | 3 (0.1) |
| Colon operation | 2 (0.0) | 4 (0.1) |
| Colostomy | 3 (0.1) | 1 (0.0) |
| Colostomy closure | 0 | 1 (0.0) |
| Colporrhaphy | 0 | 1 (0.0) |
| Contact lens therapy | 0 | 1 (0.0) |
| Contraception | 2 (0.0) | 0 |
| Contraceptive implant | 3 (0.1) | 2 (0.0) |
| Corneal operation | 2 (0.0) | 1 (0.0) |
| Corneal transplant | 2 (0.0) | 5 (0.1) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Coronary angioplasty | 5 (0.1) | 5 (0.1) |
| Coronary arterial stent insertion | 47 (0.9) | 34 (0.7) |
| Coronary artery bypass | 30 (0.6) | 26 (0.5) |
| Coronary artery stent removal | 0 | 1 (0.0) |
| Coronary artery surgery | 1 (0.0) | 1 (0.0) |
| Cranial nerve decompression | 0 | 1 (0.0) |
| Cranial operation | 2 (0.0) | 1 (0.0) |
| Cranioplasty | 1 (0.0) | 0 |
| Craniotomy | 4 (0.1) | 3 (0.1) |
| Cryotherapy | 1 (0.0) | 3 (0.1) |
| Cyst drainage | 0 | 2 (0.0) |
| Cyst removal | 0 | 5 (0.1) |
| Cystocele repair | 2 (0.0) | 1 (0.0) |
| Debridement | 1 (0.0) | 2 (0.0) |
| Deep brain stimulation | 0 | 1 (0.0) |
| Dental care | 1 (0.0) | 0 |
| Dental implantation | 7 (0.1) | 5 (0.1) |
| Dental operation | 2 (0.0) | 3 (0.1) |
| Dental prosthesis placement | 2 (0.0) | 0 |
| Detoxification | 0 | 1 (0.0) |
| Diverticulectomy | 1 (0.0) | 0 |
| Drug delivery device placement | 1 (0.0) | 0 |
| Drug therapy | 0 | 1 (0.0) |
| Duodenal switch | 1 (0.0) | 0 |
| Dupuytren's contracture operation | 2 (0.0) | 1 (0.0) |
| Ear operation | 4 (0.1) | 2 (0.0) |
| Ear tube insertion | 11 (0.2) | 9 (0.2) |
| Ear tube removal | 1 (0.0) | 1 (0.0) |
| Ectopic pregnancy termination | 0 | 1 (0.0) |
| Elbow operation | 8 (0.2) | 8 (0.2) |
| Electrodesiccation | 0 | 1 (0.0) |
| Endodontic procedure | 0 | 1 (0.0) |
| Endometrial ablation | 38 (0.7) | 36 (0.7) |
| Endometriosis ablation | 2 (0.0) | 5 (0.1) |
| Endovenous ablation | 1 (0.0) | 1 (0.0) |
| Enterostomy | 1 (0.0) | 0 |
| Epidermoid cyst excision | 1 (0.0) | 2 (0.0) |
| Epididymal cyst removal | 1 (0.0) | 2 (0.0) |
| Epiphysiodesis | 1 (0.0) | 0 |
| Ethmoid sinus surgery | 1 (0.0) | 0 |
| Eustachian tube operation | 1 (0.0) | 1 (0.0) |

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|---|---|---|
| Exeresis | 2 (0.0) | 4 (0.1) |
| Explorative laparotomy | 3 (0.1) | 1 (0.0) |
| External fixation of fracture | 0 | 2 (0.0) |
| External nose lesion excision | 0 | 1 (0.0) |
| Eye excision | 2 (0.0) | 0 |
| Eye laser surgery | 14 (0.3) | 10 (0.2) |
| Eye muscle operation | 1 (0.0) | 1 (0.0) |
| Eye operation | 10 (0.2) | 8 (0.2) |
| Eyelid cyst removal | 0 | 1 (0.0) |
| Eyelid operation | 1 (0.0) | 2 (0.0) |
| Face lift | 7 (0.1) | 5 (0.1) |
| Facial lesion excision | 0 | 1 (0.0) |
| Facial operation | 1 (0.0) | 3 (0.1) |
| Fallopian tube operation | 1 (0.0) | 2 (0.0) |
| Fascia release | 3 (0.1) | 1 (0.0) |
| Fascial operation | 1 (0.0) | 1 (0.0) |
| Fasciotomy | 4 (0.1) | 4 (0.1) |
| Female genital operation | 1 (0.0) | 0 |
| Female sterilisation | 207 (4.1) | 174 (3.4) |
| Femoral hernia repair | 1 (0.0) | 1 (0.0) |
| Finger amputation | 5 (0.1) | 2 (0.0) |
| Finger repair operation | 4 (0.1) | 2 (0.0) |
| Fistula repair | 0 | 1 (0.0) |
| Fistulotomy | 1 (0.0) | 0 |
| Foot amputation | 1 (0.0) | 1 (0.0) |
| Foot operation | 17 (0.3) | 11 (0.2) |
| Foraminotomy | 1 (0.0) | 0 |
| Fracture reduction | 2 (0.0) | 0 |
| Fracture treatment | 45 (0.9) | 55 (1.1) |
| Frontal sinus operation | 1 (0.0) | 0 |
| Functional endoscopic sinus surgery | 0 | 1 (0.0) |
| Gallbladder operation | 3 (0.1) | 3 (0.1) |
| Gallbladder polypectomy | 0 | 1 (0.0) |
| Gastrectomy | 20 (0.4) | 30 (0.6) |
| Gastric banding | 7 (0.1) | 9 (0.2) |
| Gastric banding reversal | 1 (0.0) | 1 (0.0) |
| Gastric bypass | 40 (0.8) | 36 (0.7) |
| Gastric operation | 1 (0.0) | 0 |
| Gastric ulcer surgery | 1 (0.0) | 0 |
| Gastrointestinal surgery | 0 | 1 (0.0) |
| Genitourinary operation | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Gingival graft | 1 (0.0) | 0 |
| Glaucoma drainage device placement | 1 (0.0) | 0 |
| Glaucoma surgery | 2 (0.0) | 3 (0.1) |
| Glossectomy | 1 (0.0) | 1 (0.0) |
| Haemangioma removal | 1 (0.0) | 0 |
| Haematoma evacuation | 0 | 1 (0.0) |
| Haemorrhoid operation | 15 (0.3) | 22 (0.4) |
| Haemostasis | 0 | 1 (0.0) |
| Hair transplant | 1 (0.0) | 1 (0.0) |
| Hand repair operation | 1 (0.0) | 0 |
| Heart valve replacement | 2 (0.0) | 1 (0.0) |
| Hepatectomy | 0 | 1 (0.0) |
| Hernia diaphragmatic repair | 1 (0.0) | 2 (0.0) |
| Hernia hiatus repair | 3 (0.1) | 6 (0.1) |
| Hernia repair | 40 (0.8) | 53 (1.1) |
| High frequency ablation | 1 (0.0) | 2 (0.0) |
| Hip arthroplasty | 58 (1.1) | 68 (1.3) |
| Hip surgery | 9 (0.2) | 8 (0.2) |
| Hormonal contraception | 0 | 1 (0.0) |
| Hormone replacement therapy | 7 (0.1) | 3 (0.1) |
| Hormone therapy | 1 (0.0) | 0 |
| Hydrocele operation | 2 (0.0) | 5 (0.1) |
| Hyperbaric oxygen therapy | 1 (0.0) | 0 |
| Hysterectomy | 480 (9.4) | 457 (9.1) |
| Hysterosalpingo-oophorectomy | 4 (0.1) | 3 (0.1) |
| Hysterotomy | 1 (0.0) | 1 (0.0) |
| Ileocolectomy | 1 (0.0) | 0 |
| Ileostomy | 1 (0.0) | 2 (0.0) |
| Ileostomy closure | 1 (0.0) | 0 |
| Implantable cardiac monitor insertion | 1 (0.0) | 2 (0.0) |
| Implantable cardiac monitor removal | 0 | 1 (0.0) |
| Implantable defibrillator insertion | 8 (0.2) | 2 (0.0) |
| Implantable defibrillator removal | 2 (0.0) | 0 |
| Implantable defibrillator replacement | 1 (0.0) | 2 (0.0) |
| In vitro fertilisation | 0 | 1 (0.0) |
| Incisional drainage | 1 (0.0) | 1 (0.0) |
| Incisional hernia repair | 2 (0.0) | 1 (0.0) |
| Inguinal hernia repair | 83 (1.6) | 80 (1.6) |
| Injection | 2 (0.0) | 0 |
| Inner ear operation | 0 | 1 (0.0) |
| Internal fixation of fracture | 1 (0.0) | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Intervertebral disc operation | 38 (0.7) | 38 (0.8) |
| Intestinal adhesion lysis | 0 | 1 (0.0) |
| Intestinal operation | 2 (0.0) | 3 (0.1) |
| Intestinal resection | 7 (0.1) | 4 (0.1) |
| Intra-cerebral aneurysm operation | 1 (0.0) | 2 (0.0) |
| Intra-uterine contraceptive device insertion | 12 (0.2) | 12 (0.2) |
| Intramedullary rod insertion | 1 (0.0) | 0 |
| Intraocular lens implant | 10 (0.2) | 10 (0.2) |
| Intrauterine contraception | 5 (0.1) | 5 (0.1) |
| Iridotomy | 0 | 2 (0.0) |
| Jaw operation | 6 (0.1) | 5 (0.1) |
| Joint arthroplasty | 6 (0.1) | 2 (0.0) |
| Joint debridement | 2 (0.0) | 2 (0.0) |
| Joint dislocation reduction | 5 (0.1) | 2 (0.0) |
| Joint fluid drainage | 0 | 1 (0.0) |
| Joint injection | 0 | 1 (0.0) |
| Joint resurfacing surgery | 1 (0.0) | 0 |
| Joint surgery | 2 (0.0) | 2 (0.0) |
| Keratectomy | 0 | 1 (0.0) |
| Keratomileusis | 41 (0.8) | 45 (0.9) |
| Keratoplasty | 0 | 2 (0.0) |
| Keratotomy | 0 | 1 (0.0) |
| Knee arthroplasty | 116 (2.3) | 106 (2.1) |
| Knee operation | 64 (1.3) | 48 (1.0) |
| Lacrimal duct procedure | 0 | 2 (0.0) |
| Laparoscopic surgery | 1 (0.0) | 2 (0.0) |
| Laparotomy | 0 | 1 (0.0) |
| Large intestinal polypectomy | 29 (0.6) | 27 (0.5) |
| Laryngeal operation | 1 (0.0) | 0 |
| Leg amputation | 3 (0.1) | 2 (0.0) |
| Lens capsulotomy | 3 (0.1) | 2 (0.0) |
| Lens extraction | 0 | 1 (0.0) |
| Lenticular operation | 1 (0.0) | 0 |
| Lesion excision | 1 (0.0) | 0 |
| Ligament operation | 59 (1.2) | 59 (1.2) |
| Limb operation | 27 (0.5) | 39 (0.8) |
| Limb reattachment surgery | 0 | 1 (0.0) |
| Lip operation | 0 | 1 (0.0) |
| Lipectomy | 1 (0.0) | 1 (0.0) |
| Lipoma excision | 13 (0.3) | 10 (0.2) |
| Liposuction | 4 (0.1) | 5 (0.1) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Lithotomy position | 1 (0.0) | 0 |
| Lithotripsy | 16 (0.3) | 12 (0.2) |
| Liver operation | 0 | 1 (0.0) |
| Loop electrosurgical excision procedure | 7 (0.1) | 4 (0.1) |
| Lower oesophageal sphincter magnetic augmentation | 1 (0.0) | 0 |
| Lung lobectomy | 2 (0.0) | 1 (0.0) |
| Lung neoplasm surgery | 1 (0.0) | 1 (0.0) |
| Lung operation | 0 | 2 (0.0) |
| Lymphadenectomy | 10 (0.2) | 2 (0.0) |
| Lymphoid tissue operation | 0 | 2 (0.0) |
| Lymphoma operation | 0 | 1 (0.0) |
| Mammary ductectomy | 1 (0.0) | 0 |
| Mammoplasty | 59 (1.2) | 83 (1.6) |
| Manipulation | 1 (0.0) | 0 |
| Mass excision | 1 (0.0) | 0 |
| Mastectomy | 27 (0.5) | 28 (0.6) |
| Mastoid operation | 0 | 1 (0.0) |
| Mastoidectomy | 0 | 2 (0.0) |
| Matrixectomy | 1 (0.0) | 0 |
| Maxillofacial operation | 0 | 2 (0.0) |
| Mediastinal operation | 1 (0.0) | 0 |
| Medical cannabis therapy | 2 (0.0) | 0 |
| Medical device battery replacement | 0 | 1 (0.0) |
| Medical device removal | 1 (0.0) | 2 (0.0) |
| Meningioma surgery | 1 (0.0) | 0 |
| Meniscus operation | 54 (1.1) | 61 (1.2) |
| Meniscus removal | 9 (0.2) | 6 (0.1) |
| Metabolic surgery | 13 (0.3) | 17 (0.3) |
| Metatarsal excision | 1 (0.0) | 0 |
| Micrographic skin surgery | 24 (0.5) | 18 (0.4) |
| Middle ear operation | 0 | 1 (0.0) |
| Mitral valve repair | 4 (0.1) | 6 (0.1) |
| Mitral valve replacement | 3 (0.1) | 2 (0.0) |
| Mole excision | 6 (0.1) | 3 (0.1) |
| Muscle flap operation | 1 (0.0) | 0 |
| Muscle operation | 11 (0.2) | 5 (0.1) |
| Muscle reattachment | 0 | 1 (0.0) |
| Myomectomy | 8 (0.2) | 10 (0.2) |
| Myopia correction | 1 (0.0) | 0 |
| Myringotomy | 2 (0.0) | 0 |
| Nail operation | 2 (0.0) | 3 (0.1) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Nasal operation | 9 (0.2) | 1 (0.0) |
| Nasal polypectomy | 5 (0.1) | 4 (0.1) |
| Nasal septal operation | 39 (0.8) | 46 (0.9) |
| Nasal sinus irrigation | 1 (0.0) | 0 |
| Neck dissection | 1 (0.0) | 2 (0.0) |
| Neck lift | 0 | 1 (0.0) |
| Neck surgery | 5 (0.1) | 5 (0.1) |
| Nephrectomy | 7 (0.1) | 16 (0.3) |
| Nerve block | 1 (0.0) | 1 (0.0) |
| Nervous system neoplasm surgery | 5 (0.1) | 0 |
| Neurectomy | 6 (0.1) | 6 (0.1) |
| Neuroprosthesis implantation | 2 (0.0) | 1 (0.0) |
| Neurostimulator removal | 1 (0.0) | 0 |
| Oesophageal dilation procedure | 1 (0.0) | 1 (0.0) |
| Oesophageal operation | 2 (0.0) | 1 (0.0) |
| Oesophagectomy | 2 (0.0) | 0 |
| Oesophagogastrectomy | 0 | 1 (0.0) |
| Oesophagogastric fundoplasty | 4 (0.1) | 5 (0.1) |
| Oocyte harvest | 1 (0.0) | 0 |
| Oophorectomy | 24 (0.5) | 20 (0.4) |
| Oophorectomy bilateral | 20 (0.4) | 24 (0.5) |
| Open reduction of fracture | 20 (0.4) | 22 (0.4) |
| Oral cavity neoplasm surgery | 1 (0.0) | 0 |
| Oral surgery | 2 (0.0) | 1 (0.0) |
| Orchidectomy | 5 (0.1) | 6 (0.1) |
| Orchidopexy | 2 (0.0) | 0 |
| Orthognathic surgery | 2 (0.0) | 6 (0.1) |
| Orthopaedic procedure | 2 (0.0) | 1 (0.0) |
| Ossicular operation | 1 (0.0) | 0 |
| Ossiculoplasty | 0 | 1 (0.0) |
| Ostectomy | 4 (0.1) | 2 (0.0) |
| Osteotomy | 6 (0.1) | 4 (0.1) |
| Otoplasty | 2 (0.0) | 3 (0.1) |
| Ovarian cystectomy | 9 (0.2) | 14 (0.3) |
| Ovarian lesion excision | 1 (0.0) | 2 (0.0) |
| Ovarian neoplasm surgery | 3 (0.1) | 0 |
| Ovarian operation | 1 (0.0) | 0 |
| Ovariocentesis | 1 (0.0) | 0 |
| Palatal operation | 2 (0.0) | 0 |
| Pancreatectomy | 1 (0.0) | 0 |
| Pancreatic operation | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Pancreaticoduodenectomy | 0 | 2 (0.0) |
| Papilloma excision | 4 (0.1) | 2 (0.0) |
| Paranasal sinus polypectomy | 3 (0.1) | 4 (0.1) |
| Parathyroid gland operation | 2 (0.0) | 0 |
| Parathyroidectomy | 12 (0.2) | 10 (0.2) |
| Parotidectomy | 3 (0.1) | 0 |
| Patellectomy | 0 | 1 (0.0) |
| Pelvic floor repair | 1 (0.0) | 0 |
| Penile prosthesis insertion | 1 (0.0) | 3 (0.1) |
| Percutaneous coronary intervention | 1 (0.0) | 0 |
| Pericardial excision | 1 (0.0) | 0 |
| Peripheral artery stent insertion | 1 (0.0) | 0 |
| Peripheral nerve decompression | 2 (0.0) | 7 (0.1) |
| Peripheral nerve destruction | 1 (0.0) | 0 |
| Peripheral nerve neurostimulation | 0 | 1 (0.0) |
| Peripheral nerve operation | 3 (0.1) | 1 (0.0) |
| Peripheral nerve transposition | 1 (0.0) | 4 (0.1) |
| Permanent contraceptive tubal implant | 2 (0.0) | 0 |
| Pharyngeal operation | 3 (0.1) | 1 (0.0) |
| Pharyngeal polypectomy | 1 (0.0) | 0 |
| Phlebectomy | 2 (0.0) | 0 |
| Photorefractive keratectomy | 3 (0.1) | 4 (0.1) |
| Physiotherapy | 1 (0.0) | 0 |
| Pilonidal sinus repair | 8 (0.2) | 4 (0.1) |
| Pituitary tumour removal | 3 (0.1) | 4 (0.1) |
| Plastic surgery | 2 (0.0) | 2 (0.0) |
| Plastic surgery to the face | 3 (0.1) | 3 (0.1) |
| Pleurodesis | 1 (0.0) | 0 |
| Pneumocentesis | 0 | 1 (0.0) |
| Polypectomy | 6 (0.1) | 5 (0.1) |
| Positive airway pressure therapy | 1 (0.0) | 2 (0.0) |
| Precancerous lesion excision | 0 | 2 (0.0) |
| Proctocolectomy | 0 | 1 (0.0) |
| Prophylaxis | 1 (0.0) | 0 |
| Prophylaxis against HIV infection | 0 | 4 (0.1) |
| Prostate ablation | 2 (0.0) | 0 |
| Prostatectomy | 29 (0.6) | 27 (0.5) |
| Prostatic operation | 2 (0.0) | 6 (0.1) |
| Prostatic urethral lift procedure | 0 | 1 (0.0) |
| Pterygium operation | 3 (0.1) | 0 |
| Ptosis repair | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Pulmonary valve repair | 0 | 1 (0.0) |
| Punctal plug insertion | 0 | 1 (0.0) |
| Pyeloplasty | 1 (0.0) | 0 |
| Pyloromyotomy | 1 (0.0) | 1 (0.0) |
| Pyloroplasty | 0 | 2 (0.0) |
| Pylorus dilation procedure | 1 (0.0) | 0 |
| Rachiotomy | 1 (0.0) | 0 |
| Radiation therapy to ear, nose, or throat | 0 | 1 (0.0) |
| Radical cystectomy | 0 | 1 (0.0) |
| Radical prostatectomy | 4 (0.1) | 1 (0.0) |
| Radiculotomy | 1 (0.0) | 0 |
| Radioactive iodine therapy | 2 (0.0) | 1 (0.0) |
| Radiotherapy | 2 (0.0) | 4 (0.1) |
| Radiotherapy to breast | 1 (0.0) | 2 (0.0) |
| Radiotherapy to prostate | 1 (0.0) | 4 (0.1) |
| Radiotherapy to skin | 0 | 1 (0.0) |
| Radiotherapy to thyroid | 0 | 1 (0.0) |
| Rectal lesion excision | 2 (0.0) | 0 |
| Rectal polypectomy | 0 | 1 (0.0) |
| Rectal prolapse repair | 1 (0.0) | 1 (0.0) |
| Rectocele repair | 4 (0.1) | 3 (0.1) |
| Reduction of increased intracranial pressure | 0 | 1 (0.0) |
| Removal of foreign body | 3 (0.1) | 5 (0.1) |
| Removal of foreign body from joint | 0 | 1 (0.0) |
| Removal of internal fixation | 0 | 1 (0.0) |
| Renal cyst excision | 0 | 1 (0.0) |
| Renal stone removal | 16 (0.3) | 12 (0.2) |
| Renal surgery | 0 | 2 (0.0) |
| Renal tumour excision | 1 (0.0) | 1 (0.0) |
| Retinal operation | 6 (0.1) | 4 (0.1) |
| Retinopexy | 6 (0.1) | 7 (0.1) |
| Rhinoplasty | 22 (0.4) | 24 (0.5) |
| Rib excision | 1 (0.0) | 1 (0.0) |
| Rotator cuff repair | 82 (1.6) | 65 (1.3) |
| Salivary gland operation | 1 (0.0) | 1 (0.0) |
| Salivary gland resection | 1 (0.0) | 0 |
| Salpingectomy | 30 (0.6) | 45 (0.9) |
| Salpingo-oophorectomy | 0 | 1 (0.0) |
| Salpingo-oophorectomy bilateral | 7 (0.1) | 6 (0.1) |
| Salpingo-oophorectomy unilateral | 5 (0.1) | 1 (0.0) |
| Salpingolysis | 1 (0.0) | 0 |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Salpingostomy | 1 (0.0) | 2 (0.0) |
| Sarcoma excision | 0 | 1 (0.0) |
| Scar excision | 1 (0.0) | 2 (0.0) |
| Scleral buckling surgery | 1 (0.0) | 1 (0.0) |
| Sclerotherapy | 1 (0.0) | 1 (0.0) |
| Scoliosis surgery | 0 | 3 (0.1) |
| Scrotal operation | 0 | 1 (0.0) |
| Sebaceous cyst excision | 2 (0.0) | 1 (0.0) |
| Shoulder arthroplasty | 11 (0.2) | 9 (0.2) |
| Shoulder operation | 37 (0.7) | 33 (0.7) |
| Sigmoidectomy | 2 (0.0) | 2 (0.0) |
| Simple mastectomy | 0 | 1 (0.0) |
| Sinuplasty | 4 (0.1) | 5 (0.1) |
| Sinus antrostomy | 1 (0.0) | 0 |
| Sinus operation | 27 (0.5) | 25 (0.5) |
| Skin cosmetic procedure | 2 (0.0) | 5 (0.1) |
| Skin cyst excision | 2 (0.0) | 0 |
| Skin graft | 2 (0.0) | 3 (0.1) |
| Skin lesion removal | 7 (0.1) | 8 (0.2) |
| Skin neoplasm excision | 62 (1.2) | 76 (1.5) |
| Skin operation | 6 (0.1) | 1 (0.0) |
| Small intestinal resection | 3 (0.1) | 0 |
| Small intestine operation | 2 (0.0) | 1 (0.0) |
| Soft tissue flap operation | 0 | 1 (0.0) |
| Sphenoid sinus operation | 1 (0.0) | 0 |
| Spinal decompression | 4 (0.1) | 4 (0.1) |
| Spinal fracture treatment | 1 (0.0) | 2 (0.0) |
| Spinal fusion surgery | 68 (1.3) | 62 (1.2) |
| Spinal laminectomy | 22 (0.4) | 32 (0.6) |
| Spinal nerve stimulator implantation | 6 (0.1) | 1 (0.0) |
| Spinal operation | 39 (0.8) | 33 (0.7) |
| Splenectomy | 7 (0.1) | 5 (0.1) |
| Splenorrhaphy | 0 | 1 (0.0) |
| Stapedectomy | 0 | 1 (0.0) |
| Stem cell therapy | 2 (0.0) | 1 (0.0) |
| Stem cell transplant | 2 (0.0) | 0 |
| Stent placement | 6 (0.1) | 8 (0.2) |
| Sterilisation | 5 (0.1) | 6 (0.1) |
| Sterilisation reversal | 1 (0.0) | 1 (0.0) |
| Sternotomy | 0 | 1 (0.0) |
| Steroid therapy | 1 (0.0) | 0 |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Stomach lesion excision | 0 | 2 (0.0) |
| Strabismus correction | 9 (0.2) | 6 (0.1) |
| Subdural haematoma evacuation | 0 | 1 (0.0) |
| Surgery | 2 (0.0) | 3 (0.1) |
| Synovial cyst removal | 13 (0.3) | 6 (0.1) |
| Talipes correction | 0 | 1 (0.0) |
| Temporomandibular joint surgery | 3 (0.1) | 2 (0.0) |
| Tendon graft | 0 | 2 (0.0) |
| Tendon operation | 3 (0.1) | 1 (0.0) |
| Tendon sheath incision | 14 (0.3) | 13 (0.3) |
| Tendon transfer | 2 (0.0) | 2 (0.0) |
| Tenolysis | 0 | 1 (0.0) |
| Tenonectomy | 1 (0.0) | 0 |
| Tenoplasty | 25 (0.5) | 21 (0.4) |
| Tenotomy | 2 (0.0) | 4 (0.1) |
| Testicular prosthesis insertion | 0 | 1 (0.0) |
| Therapeutic embolisation | 2 (0.0) | 0 |
| Therapeutic nerve ablation | 3 (0.1) | 1 (0.0) |
| Therapeutic procedure | 1 (0.0) | 0 |
| Thermal ablation | 0 | 1 (0.0) |
| Thoracic operation | 1 (0.0) | 0 |
| Thoracotomy | 1 (0.0) | 2 (0.0) |
| Thrombectomy | 3 (0.1) | 0 |
| Thymectomy | 0 | 1 (0.0) |
| Thyroglossal cyst excision | 0 | 1 (0.0) |
| Thyroid cystectomy | 0 | 1 (0.0) |
| Thyroid nodule removal | 2 (0.0) | 2 (0.0) |
| Thyroid operation | 2 (0.0) | 1 (0.0) |
| Thyroidectomy | 56 (1.1) | 47 (0.9) |
| Toe amputation | 1 (0.0) | 5 (0.1) |
| Toe operation | 4 (0.1) | 8 (0.2) |
| Tonsillectomy | 268 (5.3) | 260 (5.2) |
| Tooth extraction | 5 (0.1) | 10 (0.2) |
| Tooth restoration | 3 (0.1) | 1 (0.0) |
| Trabeculectomy | 4 (0.1) | 2 (0.0) |
| Trabeculoplasty | 1 (0.0) | 1 (0.0) |
| Tracheal fistula repair | 1 (0.0) | 0 |
| Tracheostomy | 3 (0.1) | 0 |
| Transcatheter aortic valve implantation | 1 (0.0) | 0 |
| Transfusion | 4 (0.1) | 0 |
| Transgender hormonal therapy | 1 (0.0) | 0 |

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| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Transgender operation | 2 (0.0) | 1 (0.0) |
| Transplant | 2 (0.0) | 0 |
| Transurethral incision of prostate | 1 (0.0) | 0 |
| Transurethral prostatectomy | 12 (0.2) | 5 (0.1) |
| Tumour excision | 1 (0.0) | 0 |
| Tumour vaccine therapy | 1 (0.0) | 0 |
| Turbinectomy | 2 (0.0) | 1 (0.0) |
| Turbinoplasty | 2 (0.0) | 0 |
| Tympanoplasty | 1 (0.0) | 7 (0.1) |
| Umbilical hernia repair | 39 (0.8) | 20 (0.4) |
| Ureteral stent insertion | 1 (0.0) | 4 (0.1) |
| Ureteric calculus removal | 1 (0.0) | 1 (0.0) |
| Ureteric repair | 0 | 1 (0.0) |
| Urethral dilation procedure | 0 | 1 (0.0) |
| Urethral operation | 5 (0.1) | 0 |
| Urethral repair | 0 | 3 (0.1) |
| Urethral stent insertion | 0 | 1 (0.0) |
| Urinary bladder suspension | 24 (0.5) | 17 (0.3) |
| Urinary control neurostimulator implantation | 1 (0.0) | 0 |
| Uterine artery embolisation | 3 (0.1) | 1 (0.0) |
| Uterine dilation and curettage | 20 (0.4) | 19 (0.4) |
| Uterine irrigation | 0 | 1 (0.0) |
| Uterine operation | 2 (0.0) | 1 (0.0) |
| Uterine polypectomy | 1 (0.0) | 1 (0.0) |
| Uterine prolapse repair | 1 (0.0) | 0 |
| Uterine repair | 1 (0.0) | 0 |
| Uterine tumour excision | 0 | 1 (0.0) |
| Uvulectomy | 3 (0.1) | 0 |
| Uvulopalatopharyngoplasty | 3 (0.1) | 0 |
| Uvuloplasty | 0 | 1 (0.0) |
| Vagal nerve stimulator implantation | 0 | 1 (0.0) |
| Vaginal fistula repair | 1 (0.0) | 0 |
| Vaginal operation | 0 | 4 (0.1) |
| Vaginal prolapse repair | 2 (0.0) | 1 (0.0) |
| Varicocele repair | 6 (0.1) | 3 (0.1) |
| Varicose vein operation | 6 (0.1) | 7 (0.1) |
| Vascular graft | 2 (0.0) | 0 |
| Vascular operation | 1 (0.0) | 1 (0.0) |
| Vascular stent insertion | 1 (0.0) | 4 (0.1) |
| Vasectomy | 278 (5.5) | 261 (5.2) |
| Vasectomy reversal | 0 | 1 (0.0) |

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| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Vena cava filter insertion | 1 (0.0) | 1 (0.0) |
| Venous operation | 1 (0.0) | 3 (0.1) |
| Ventriculo-peritoneal shunt | 0 | 1 (0.0) |
| Vertebroplasty | 0 | 2 (0.0) |
| Vessel harvesting | 1 (0.0) | 0 |
| Vestibular apparatus operation | 1 (0.0) | 0 |
| Vision correction operation | 2 (0.0) | 1 (0.0) |
| Vitamin supplementation | 0 | 1 (0.0) |
| Vitrectomy | 4 (0.1) | 4 (0.1) |
| Vocal cord nodule removal | 0 | 1 (0.0) |
| Vocal cord polypectomy | 3 (0.1) | 0 |
| Vulvectomy | 0 | 1 (0.0) |
| Wisdom teeth removal | 50 (1.0) | 51 (1.0) |
| Wound closure | 0 | 1 (0.0) |
| Wrist surgery | 14 (0.3) | 11 (0.2) |
| Vascular disorders | 1484 (29.2) | 1477 (29.3) |
| Aneurysm | 2 (0.0) | 2 (0.0) |
| Angiopathy | 0 | 3 (0.1) |
| Aortic aneurysm | 15 (0.3) | 9 (0.2) |
| Aortic arteriosclerosis | 10 (0.2) | 8 (0.2) |
| Aortic dilatation | 6 (0.1) | 2 (0.0) |
| Aortic disorder | 0 | 1 (0.0) |
| Aortic stenosis | 3 (0.1) | 3 (0.1) |
| Arterial occlusive disease | 0 | 3 (0.1) |
| Arterial stenosis | 0 | 1 (0.0) |
| Arteriosclerosis | 9 (0.2) | 7 (0.1) |
| Arteriovenous fistula | 0 | 1 (0.0) |
| Deep vein thrombosis | 21 (0.4) | 20 (0.4) |
| Diabetic vascular disorder | 1 (0.0) | 1 (0.0) |
| Embolism arterial | 1 (0.0) | 0 |
| Embolism venous | 2 (0.0) | 0 |
| Essential hypertension | 23 (0.5) | 22 (0.4) |
| Haematoma | 1 (0.0) | 1 (0.0) |
| Haemorrhage | 0 | 2 (0.0) |
| Hot flush | 46 (0.9) | 47 (0.9) |
| Hypertension | 1356 (26.7) | 1360 (27.0) |
| Hypotension | 9 (0.2) | 4 (0.1) |
| Intermittent claudication | 0 | 2 (0.0) |
| Internal haemorrhage | 1 (0.0) | 0 |
| Ischaemia | 0 | 1 (0.0) |

## 14.11. Medical History – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5081)<br>n[b] (%) | Vaccine Group (as Administered)<br>Placebo<br>(N[a]=5044)<br>n[b] (%) |
|---|---|---|
| Lymphoedema | 2 (0.0) | 2 (0.0) |
| May-Thurner syndrome | 0 | 1 (0.0) |
| Neovascularisation | 0 | 1 (0.0) |
| Orthostatic hypotension | 1 (0.0) | 3 (0.1) |
| Peripheral arterial occlusive disease | 3 (0.1) | 6 (0.1) |
| Peripheral artery aneurysm | 0 | 2 (0.0) |
| Peripheral artery thrombosis | 0 | 1 (0.0) |
| Peripheral vascular disorder | 5 (0.1) | 4 (0.1) |
| Peripheral venous disease | 9 (0.2) | 7 (0.1) |
| Phlebitis | 0 | 1 (0.0) |
| Phlebosclerosis | 1 (0.0) | 0 |
| Poor peripheral circulation | 2 (0.0) | 0 |
| Prehypertension | 1 (0.0) | 0 |
| Raynaud's phenomenon | 7 (0.1) | 9 (0.2) |
| Spider vein | 0 | 1 (0.0) |
| Subclavian artery aneurysm | 0 | 1 (0.0) |
| Superficial vein thrombosis | 1 (0.0) | 0 |
| Thrombophlebitis | 2 (0.0) | 0 |
| Thrombosis | 4 (0.1) | 8 (0.2) |
| Varicose vein | 24 (0.5) | 26 (0.5) |
| Vasculitis | 0 | 1 (0.0) |
| Vena cava thrombosis | 0 | 1 (0.0) |
| Venous haemorrhage | 1 (0.0) | 0 |
| Venous thrombosis | 1 (0.0) | 1 (0.0) |
| Venous thrombosis limb | 0 | 1 (0.0) |
| White coat hypertension | 5 (0.1) | 1 (0.0) |

Note: MedDRA (v24.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic. Participants with multiple occurrences of the same preferred term are counted only once.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:12) Source Data: admh Table Generation: 14MAR2022 (20:56)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: /lida2_ubBIA/C4591031_A_SBLA/admh_s002_all_saf

## 14.12. Baseline Charlson Comorbidities – Safety Population

| Charlson Comorbidity Index Category | Vaccine Group (as Administered) BNT162b2 (30 µg) (N[a]=5081) n[b] (%) | Placebo (N[a]=5044) n[b] (%) | Total (N[a]=10125) n[b] (%) |
|---|---|---|---|
| Participants with any Charlson comorbidity | 1200 (23.6) | 1197 (23.7) | 2397 (23.7) |
| AIDS/HIV | 26 (0.5) | 24 (0.5) | 50 (0.5) |
| Any malignancy | 245 (4.8) | 226 (4.5) | 471 (4.7) |
| Cerebrovascular disease | 59 (1.2) | 52 (1.0) | 111 (1.1) |
| Chronic pulmonary disease | 448 (8.8) | 485 (9.6) | 933 (9.2) |
| Congestive heart failure | 44 (0.9) | 33 (0.7) | 77 (0.8) |
| Dementia | 2 (0.0) | 4 (0.1) | 6 (0.1) |
| Diabetes with chronic complication | 39 (0.8) | 26 (0.5) | 65 (0.6) |
| Diabetes without chronic complication | 421 (8.3) | 426 (8.4) | 847 (8.4) |
| Hemiplegia or paraplegia | 6 (0.1) | 3 (0.1) | 9 (0.1) |
| Leukemia | 3 (0.1) | 5 (0.1) | 8 (0.1) |
| Lymphoma | 10 (0.2) | 5 (0.1) | 15 (0.1) |
| Metastatic solid tumor | 1 (0.0) | 1 (0.0) | 2 (0.0) |
| Mild liver disease | 49 (1.0) | 38 (0.8) | 87 (0.9) |
| Myocardial infarction | 53 (1.0) | 52 (1.0) | 105 (1.0) |
| Peptic ulcer disease | 17 (0.3) | 25 (0.5) | 42 (0.4) |
| Peripheral vascular disease | 45 (0.9) | 38 (0.8) | 83 (0.8) |
| Renal disease | 32 (0.6) | 41 (0.8) | 73 (0.7) |
| Rheumatic disease | 20 (0.4) | 23 (0.5) | 43 (0.4) |

Note: MedDRA (v24.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic. Participants with multiple occurrences within each category are counted only once. For "Participants with any Charlson comorbidity," n = number of participants reporting at least 1 occurrence of any Charlson comorbidity.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:12) Source Data: admh Table Generation: 14MAR2022 (20:44)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_subBIA/C4591031_A_SBLA/admh_s002_risk_all_saf

## 14.13. Baseline Charlson Comorbidities, by Age Group – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2823) | Placebo (N[a]=2797) | Total (N[a]=5620) |
| Charlson Comorbidity Index Category | n[b] (%) | n[b] (%) | n[b] (%) |
| Participants with any Charlson comorbidity | 453 (16.0) | 446 (15.9) | 899 (16.0) |
| AIDS/HIV | 19 (0.7) | 16 (0.6) | 35 (0.6) |
| Any malignancy | 45 (1.6) | 36 (1.3) | 81 (1.4) |
| Cerebrovascular disease | 12 (0.4) | 8 (0.3) | 20 (0.4) |
| Chronic pulmonary disease | 250 (8.9) | 262 (9.4) | 512 (9.1) |
| Congestive heart failure | 4 (0.1) | 8 (0.3) | 12 (0.2) |
| Dementia | 0 | 0 | 0 |
| Diabetes with chronic complication | 3 (0.1) | 6 (0.2) | 9 (0.2) |
| Diabetes without chronic complication | 112 (4.0) | 120 (4.3) | 232 (4.1) |
| Hemiplegia or paraplegia | 2 (0.1) | 1 (0.0) | 3 (0.1) |
| Leukemia | 0 | 3 (0.1) | 3 (0.1) |
| Lymphoma | 3 (0.1) | 2 (0.1) | 5 (0.1) |
| Metastatic solid tumor | 1 (0.0) | 0 | 1 (0.0) |
| Mild liver disease | 25 (0.9) | 10 (0.4) | 35 (0.6) |
| Myocardial infarction | 10 (0.4) | 4 (0.1) | 14 (0.2) |
| Peptic ulcer disease | 2 (0.1) | 10 (0.4) | 12 (0.2) |
| Peripheral vascular disease | 4 (0.1) | 3 (0.1) | 7 (0.1) |
| Renal disease | 0 | 6 (0.2) | 6 (0.1) |
| Rheumatic disease | 8 (0.3) | 9 (0.3) | 17 (0.3) |

Note: MedDRA (v24.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic. Participants with multiple occurrences within each category are counted only once. For "Participants with any Charlson comorbidity," n = number of participants reporting at least 1 occurrence of any Charlson comorbidity.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:12) Source Data: admh Table Generation: 14MAR2022 (20:49)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/admh_s002_risk_age_saf

## 14.14. Baseline Charlson Comorbidities, by Age Group – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| Charlson Comorbidity Index Category | BNT162b2 (30 µg) (N[a]=2258) n[b] (%) | Placebo (N[a]=2247) n[b] (%) | Total (N[a]=4505) n[b] (%) |
| Participants with any Charlson comorbidity | 747 (33.1) | 751 (33.4) | 1498 (33.3) |
| AIDS/HIV | 7 (0.3) | 8 (0.4) | 15 (0.3) |
| Any malignancy | 200 (8.9) | 190 (8.5) | 390 (8.7) |
| Cerebrovascular disease | 47 (2.1) | 44 (2.0) | 91 (2.0) |
| Chronic pulmonary disease | 198 (8.8) | 223 (9.9) | 421 (9.3) |
| Congestive heart failure | 40 (1.8) | 25 (1.1) | 65 (1.4) |
| Dementia | 2 (0.1) | 4 (0.2) | 6 (0.1) |
| Diabetes with chronic complication | 36 (1.6) | 20 (0.9) | 56 (1.2) |
| Diabetes without chronic complication | 309 (13.7) | 306 (13.6) | 615 (13.7) |
| Hemiplegia or paraplegia | 4 (0.2) | 2 (0.1) | 6 (0.1) |
| Leukemia | 3 (0.1) | 2 (0.1) | 5 (0.1) |
| Lymphoma | 7 (0.3) | 3 (0.1) | 10 (0.2) |
| Metastatic solid tumor | 0 | 1 (0.0) | 1 (0.0) |
| Mild liver disease | 24 (1.1) | 28 (1.2) | 52 (1.2) |
| Myocardial infarction | 43 (1.9) | 48 (2.1) | 91 (2.0) |
| Peptic ulcer disease | 15 (0.7) | 15 (0.7) | 30 (0.7) |
| Peripheral vascular disease | 41 (1.8) | 35 (1.6) | 76 (1.7) |
| Renal disease | 32 (1.4) | 35 (1.6) | 67 (1.5) |
| Rheumatic disease | 12 (0.5) | 14 (0.6) | 26 (0.6) |

Note: MedDRA (v24.1) coding dictionary applied.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic. Participants with multiple occurrences within each category are counted only once. For "Participants with any Charlson comorbidity," n = number of participants reporting at least 1 occurrence of any Charlson comorbidity.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:12) Source Data: admh Table Generation: 14MAR2022 (20:49)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_subBIA/C4591031_A_SBLA/admh_s002_risk_age_saf

## 14.15. Demographic Characteristics – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination (Participants Who Originally Received BNT162b2) – Safety Population

| | Vaccine Group (as Administered) |
|---|---|
| | BNT162b2 (30 µg) (N[a]=5025) n[b] (%) |
| Sex | |
| Male | 2427 (48.3) |
| Female | 2598 (51.7) |
| Race | |
| White | 3952 (78.6) |
| Black or African American | 464 (9.2) |
| American Indian or Alaska Native | 85 (1.7) |
| Asian | 285 (5.7) |
| Native Hawaiian or other Pacific Islander | 8 (0.2) |
| Multiracial | 208 (4.1) |
| Not reported | 23 (0.5) |
| Ethnicity | |
| Hispanic/Latino | 750 (14.9) |
| Non-Hispanic/non-Latino | 4263 (84.8) |
| Not reported | 12 (0.2) |
| Country | |
| Brazil | 576 (11.5) |
| South Africa | 134 (2.7) |
| USA | 4315 (85.9) |
| Age group (at vaccination) | |
| 16-55 Years | 2788 (55.5) |
| >55 Years | 2237 (44.5) |
| 16-17 Years | 46 (0.9) |
| 18-55 Years | 2742 (54.6) |
| 56-64 Years | 1075 (21.4) |
| 65+ Years | 1162 (23.1) |
| Age at vaccination (years) | |
| Mean (SD) | 51.8 (15.26) |
| Median | 53.0 |
| Min, max | (16, 86) |
| Baseline SARS-CoV-2 status | |
| Positive[c] | 285 (5.7) |
| Negative[d] | 4733 (94.2) |
| Unknown | 7 (0.1) |
| Body mass index (BMI) | |
| Underweight (<18.5 kg/m$^2$) | 57 (1.1) |

## 14.15. Demographic Characteristics – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination (Participants Who Originally Received BNT162b2) – Safety Population

| | Vaccine Group (as Administered) |
|---|---|
| | BNT162b2 (30 µg) (N[a]=5025) n[b] (%) |
| Normal weight (≥18.5-24.9 kg/m$^2$) | 1412 (28.1) |
| Overweight (≥25.0-29.9 kg/m$^2$) | 1754 (34.9) |
| Obese (≥30.0 kg/m$^2$) | 1800 (35.8) |
| Missing | 2 (0.0) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:08) Source Data: adsl Table Generation: 14MAR2022 (08:59)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_s005_demo_3k

## 14.16. Demographic Characteristics – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) |
|---|---|
| | BNT162b2 (30 µg) (N[a]=4419) n[b] (%) |
| Sex | |
| Male | 2187 (49.5) |
| Female | 2232 (50.5) |
| Race | |
| White | 3447 (78.0) |
| Black or African American | 428 (9.7) |
| American Indian or Alaska Native | 82 (1.9) |
| Asian | 250 (5.7) |
| Native Hawaiian or other Pacific Islander | 11 (0.2) |
| Multiracial | 189 (4.3) |
| Not reported | 12 (0.3) |
| Ethnicity | |
| Hispanic/Latino | 657 (14.9) |
| Non-Hispanic/non-Latino | 3756 (85.0) |
| Not reported | 6 (0.1) |
| Country | |
| Brazil | 561 (12.7) |
| South Africa | 133 (3.0) |
| USA | 3725 (84.3) |
| Age group (at vaccination) | |
| 16-55 Years | 2464 (55.8) |
| >55 Years | 1955 (44.2) |
| 16-17 Years | 43 (1.0) |
| 18-55 Years | 2421 (54.8) |
| 56-64 Years | 932 (21.1) |
| 65+ Years | 1023 (23.2) |
| Age at vaccination (years) | |
| Mean (SD) | 51.6 (15.37) |
| Median | 53.0 |
| Min, max | (16, 87) |
| Baseline SARS-CoV-2 status | |
| Positive[c] | 238 (5.4) |
| Negative[d] | 4177 (94.5) |
| Unknown | 4 (0.1) |
| Body mass index (BMI) | |
| Underweight (<18.5 kg/m$^2$) | 42 (1.0) |
| Normal weight (≥18.5-24.9 kg/m$^2$) | 1239 (28.0) |

## 14.16. Demographic Characteristics – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) |
|---|---|
| | BNT162b2 (30 µg) (N[a]=4419) n[b] (%) |
| Overweight (≥25.0-29.9 kg/m$^2$) | 1519 (34.4) |
| Obese (≥30.0 kg/m$^2$) | 1619 (36.6) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 14MAR2022 (08:59)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_s005_demo_pbo_sat

## 14.17. Demographic Characteristics – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5002) n[b] (%) | Placebo (N[a]=4966) n[b] (%) | Total (N[a]=9968) n[b] (%) |
| Sex | | | |
| Male | 2423 (48.4) | 2477 (49.9) | 4900 (49.2) |
| Female | 2579 (51.6) | 2489 (50.1) | 5068 (50.8) |
| Race | | | |
| White | 3932 (78.6) | 3936 (79.3) | 7868 (78.9) |
| Black or African American | 462 (9.2) | 452 (9.1) | 914 (9.2) |
| American Indian or Alaska Native | 85 (1.7) | 91 (1.8) | 176 (1.8) |
| Asian | 284 (5.7) | 267 (5.4) | 551 (5.5) |
| Native Hawaiian or other Pacific Islander | 8 (0.2) | 11 (0.2) | 19 (0.2) |
| Multiracial | 208 (4.2) | 195 (3.9) | 403 (4.0) |
| Not reported | 23 (0.5) | 14 (0.3) | 37 (0.4) |
| Ethnicity | | | |
| Hispanic/Latino | 750 (15.0) | 741 (14.9) | 1491 (15.0) |
| Non-Hispanic/non-Latino | 4241 (84.8) | 4217 (84.9) | 8458 (84.9) |
| Not reported | 11 (0.2) | 8 (0.2) | 19 (0.2) |
| Country | | | |
| Brazil | 580 (11.6) | 583 (11.7) | 1163 (11.7) |
| South Africa | 133 (2.7) | 133 (2.7) | 266 (2.7) |
| USA | 4289 (85.7) | 4250 (85.6) | 8539 (85.7) |
| Age group (years) | | | |
| 16-55 | 2785 (55.7) | 2764 (55.7) | 5549 (55.7) |
| >55 | 2217 (44.3) | 2202 (44.3) | 4419 (44.3) |
| ≥65 | 1154 (23.1) | 1163 (23.4) | 2317 (23.2) |
| 16-17 | 45 (0.9) | 43 (0.9) | 88 (0.9) |
| 16-25 | 250 (5.0) | 274 (5.5) | 524 (5.3) |
| 16-30 | 509 (10.2) | 518 (10.4) | 1027 (10.3) |
| 18-30 | 464 (9.3) | 475 (9.6) | 939 (9.4) |
| 31-40 | 786 (15.7) | 761 (15.3) | 1547 (15.5) |
| 16-40 | 1295 (25.9) | 1279 (25.8) | 2574 (25.8) |
| 41-50 | 949 (19.0) | 979 (19.7) | 1928 (19.3) |
| 51-60 | 1110 (22.2) | 1054 (21.2) | 2164 (21.7) |
| >60 | 1648 (32.9) | 1654 (33.3) | 3302 (33.1) |
| 16-64 | 3848 (76.9) | 3803 (76.6) | 7651 (76.8) |
| 18-64 | 3803 (76.0) | 3760 (75.7) | 7563 (75.9) |
| 55-64 | 1189 (23.8) | 1129 (22.7) | 2318 (23.3) |
| 65-74 | 894 (17.9) | 904 (18.2) | 1798 (18.0) |
| ≥75 | 260 (5.2) | 259 (5.2) | 519 (5.2) |

## 14.17. Demographic Characteristics – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5002) n[b] (%) | Placebo (N[a]=4966) n[b] (%) | Total (N[a]=9968) n[b] (%) |
| 75-85 | 259 (5.2) | 255 (5.1) | 514 (5.2) |
| >85 | 1 (0.0) | 4 (0.1) | 5 (0.1) |
| Age at vaccination (years) | | | |
| Mean (SD) | 51.7 (15.24) | 51.7 (15.33) | 51.7 (15.29) |
| Median | 53.0 | 53.0 | 53.0 |
| Min, max | (16, 86) | (16, 87) | (16, 87) |
| Comorbidities[c] | | | |
| Yes | 2418 (48.3) | 2423 (48.8) | 4841 (48.6) |
| No | 2584 (51.7) | 2543 (51.2) | 5127 (51.4) |
| Body mass index (BMI) | | | |
| Underweight (<18.5 kg/m$^2$) | 57 (1.1) | 48 (1.0) | 105 (1.1) |
| Normal weight (≥18.5-24.9 kg/m$^2$) | 1406 (28.1) | 1432 (28.8) | 2838 (28.5) |
| Overweight (≥25.0-29.9 kg/m$^2$) | 1752 (35.0) | 1709 (34.4) | 3461 (34.7) |
| Obese (≥30.0 kg/m$^2$) | 1785 (35.7) | 1777 (35.8) | 3562 (35.7) |
| Missing | 2 (0.0) | 0 | 2 (0.0) |
| Baseline SARS-CoV-2 status | | | |
| Positive[d] | 272 (5.4) | 252 (5.1) | 524 (5.3) |
| Negative[e] | 4723 (94.4) | 4707 (94.8) | 9430 (94.6) |
| Unknown | 7 (0.1) | 7 (0.1) | 14 (0.1) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least 1 Charlson Comorbidity Index category or a BMI ≥30 kg/m$^2$.
d. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
e. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 16MAR2022 (08:50)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_demo_7d_wwo_eval_eff_new

## 14.18. Demographic Characteristics – Blinded Follow-Up Period – All-Available Efficacy Population

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5082) n[b] (%) | Placebo (N[a]=5043) n[b] (%) | Total (N[a]=10125) n[b] (%) |
| Sex | | | |
| Male | 2458 (48.4) | 2517 (49.9) | 4975 (49.1) |
| Female | 2624 (51.6) | 2526 (50.1) | 5150 (50.9) |
| Race | | | |
| White | 3998 (78.7) | 4002 (79.4) | 8000 (79.0) |
| Black or African American | 471 (9.3) | 460 (9.1) | 931 (9.2) |
| American Indian or Alaska Native | 86 (1.7) | 91 (1.8) | 177 (1.7) |
| Asian | 288 (5.7) | 269 (5.3) | 557 (5.5) |
| Native Hawaiian or other Pacific Islander | 8 (0.2) | 11 (0.2) | 19 (0.2) |
| Multiracial | 208 (4.1) | 196 (3.9) | 404 (4.0) |
| Not reported | 23 (0.5) | 14 (0.3) | 37 (0.4) |
| Ethnicity | | | |
| Hispanic/Latino | 760 (15.0) | 751 (14.9) | 1511 (14.9) |
| Non-Hispanic/non-Latino | 4310 (84.8) | 4284 (84.9) | 8594 (84.9) |
| Not reported | 12 (0.2) | 8 (0.2) | 20 (0.2) |
| Country | | | |
| Brazil | 580 (11.4) | 584 (11.6) | 1164 (11.5) |
| South Africa | 134 (2.6) | 134 (2.7) | 268 (2.6) |
| USA | 4368 (86.0) | 4325 (85.8) | 8693 (85.9) |
| Age group (years) | | | |
| 16-55 | 2823 (55.5) | 2797 (55.5) | 5620 (55.5) |
| >55 | 2259 (44.5) | 2246 (44.5) | 4505 (44.5) |
| ≥65 | 1175 (23.1) | 1188 (23.6) | 2363 (23.3) |
| 16-17 | 46 (0.9) | 44 (0.9) | 90 (0.9) |
| 16-25 | 252 (5.0) | 277 (5.5) | 529 (5.2) |
| 16-30 | 519 (10.2) | 521 (10.3) | 1040 (10.3) |
| 18-30 | 473 (9.3) | 477 (9.5) | 950 (9.4) |
| 31-40 | 791 (15.6) | 770 (15.3) | 1561 (15.4) |
| 16-40 | 1310 (25.8) | 1291 (25.6) | 2601 (25.7) |
| 41-50 | 963 (18.9) | 989 (19.6) | 1952 (19.3) |
| 51-60 | 1131 (22.3) | 1072 (21.3) | 2203 (21.8) |
| >60 | 1678 (33.0) | 1691 (33.5) | 3369 (33.3) |
| 16-64 | 3907 (76.9) | 3855 (76.4) | 7762 (76.7) |
| 18-64 | 3861 (76.0) | 3811 (75.6) | 7672 (75.8) |
| 55-64 | 1211 (23.8) | 1149 (22.8) | 2360 (23.3) |
| 65-74 | 910 (17.9) | 923 (18.3) | 1833 (18.1) |
| ≥75 | 265 (5.2) | 265 (5.3) | 530 (5.2) |
| 75-85 | 263 (5.2) | 260 (5.2) | 523 (5.2) |
| >85 | 2 (0.0) | 5 (0.1) | 7 (0.1) |
| Age at vaccination (years) | | | |

## 14.18. Demographic Characteristics – Blinded Follow-Up Period – All-Available Efficacy Population

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5082) n[b] (%) | Placebo (N[a]=5043) n[b] (%) | Total (N[a]=10125) n[b] (%) |
| Mean (SD) | 51.8 (15.24) | 51.7 (15.33) | 51.7 (15.28) |
| Median | 53.0 | 53.0 | 53.0 |
| Min, max | (16, 86) | (16, 87) | (16, 87) |
| Comorbidities[c] | | | |
| Yes | 2460 (48.4) | 2468 (48.9) | 4928 (48.7) |
| No | 2622 (51.6) | 2575 (51.1) | 5197 (51.3) |
| Body mass index (BMI) | | | |
| Underweight (<18.5 kg/m$^2$) | 57 (1.1) | 49 (1.0) | 106 (1.0) |
| Normal weight (≥18.5-24.9 kg/m$^2$) | 1431 (28.2) | 1457 (28.9) | 2888 (28.5) |
| Overweight (≥25.0-29.9 kg/m$^2$) | 1770 (34.8) | 1727 (34.2) | 3497 (34.5) |
| Obese (≥30.0 kg/m$^2$) | 1822 (35.9) | 1810 (35.9) | 3632 (35.9) |
| Missing | 2 (0.0) | 0 | 2 (0.0) |
| Baseline SARS-CoV-2 status | | | |
| Positive[d] | 289 (5.7) | 262 (5.2) | 551 (5.4) |
| Negative[e] | 4786 (94.2) | 4774 (94.7) | 9560 (94.4) |
| Unknown | 7 (0.1) | 7 (0.1) | 14 (0.1) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Human immunodeficiency virus (HIV)–positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least 1 Charlson Comorbidity Index category or a BMI ≥30 kg/m$^2$.
d. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
e. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 16MAR2022 (08:50)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_demo_aai_new

## 14.19. Demographic Characteristics (Participants Not Known To Be HIV-Positive) – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4689) n[b] (%) | Placebo (N[a]=4664) n[b] (%) | Total (N[a]=9353) n[b] (%) |
| Sex | | | |
| Male | 2281 (48.6) | 2336 (50.1) | 4617 (49.4) |
| Female | 2408 (51.4) | 2328 (49.9) | 4736 (50.6) |
| Race | | | |
| White | 3753 (80.0) | 3751 (80.4) | 7504 (80.2) |
| Black or African American | 363 (7.7) | 366 (7.8) | 729 (7.8) |
| American Indian or Alaska Native | 82 (1.7) | 88 (1.9) | 170 (1.8) |
| Asian | 273 (5.8) | 259 (5.6) | 532 (5.7) |
| Native Hawaiian or other Pacific Islander | 7 (0.1) | 11 (0.2) | 18 (0.2) |
| Multiracial | 189 (4.0) | 175 (3.8) | 364 (3.9) |
| Not reported | 22 (0.5) | 14 (0.3) | 36 (0.4) |
| Ethnicity | | | |
| Hispanic/Latino | 686 (14.6) | 686 (14.7) | 1372 (14.7) |
| Non-Hispanic/non-Latino | 3993 (85.2) | 3970 (85.1) | 7963 (85.1) |
| Not reported | 10 (0.2) | 8 (0.2) | 18 (0.2) |
| Country | | | |
| Brazil | 519 (11.1) | 525 (11.3) | 1044 (11.2) |
| South Africa | 74 (1.6) | 93 (2.0) | 167 (1.8) |
| USA | 4096 (87.4) | 4046 (86.7) | 8142 (87.1) |
| Age group (years) | | | |
| 16-55 | 2569 (54.8) | 2557 (54.8) | 5126 (54.8) |
| >55 | 2120 (45.2) | 2107 (45.2) | 4227 (45.2) |
| ≥65 | 1118 (23.8) | 1116 (23.9) | 2234 (23.9) |
| 16-17 | 41 (0.9) | 37 (0.8) | 78 (0.8) |
| 16-25 | 223 (4.8) | 249 (5.3) | 472 (5.0) |
| 16-30 | 460 (9.8) | 473 (10.1) | 933 (10.0) |
| 18-30 | 419 (8.9) | 436 (9.3) | 855 (9.1) |
| 31-40 | 719 (15.3) | 691 (14.8) | 1410 (15.1) |
| 16-40 | 1179 (25.1) | 1164 (25.0) | 2343 (25.1) |
| 41-50 | 883 (18.8) | 913 (19.6) | 1796 (19.2) |
| 51-60 | 1037 (22.1) | 1000 (21.4) | 2037 (21.8) |
| >60 | 1590 (33.9) | 1587 (34.0) | 3177 (34.0) |
| 16-64 | 3571 (76.2) | 3548 (76.1) | 7119 (76.1) |
| 18-64 | 3530 (75.3) | 3511 (75.3) | 7041 (75.3) |
| 55-64 | 1120 (23.9) | 1075 (23.0) | 2195 (23.5) |
| 65-74 | 867 (18.5) | 870 (18.7) | 1737 (18.6) |
| ≥75 | 251 (5.4) | 246 (5.3) | 497 (5.3) |
| 75-85 | 250 (5.3) | 243 (5.2) | 493 (5.3) |
| >85 | 1 (0.0) | 3 (0.1) | 4 (0.0) |

## 14.19. Demographic Characteristics (Participants Not Known To Be HIV-Positive) – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4689) n[b] (%) | Placebo (N[a]=4664) n[b] (%) | Total (N[a]=9353) n[b] (%) |
| Age at vaccination (years) | | | |
| Mean (SD) | 52.1 (15.22) | 52.0 (15.28) | 52.0 (15.25) |
| Median | 53.0 | 53.0 | 53.0 |
| Min, max | (16, 86) | (16, 87) | (16, 87) |
| Comorbidities[c] | | | |
| Yes | 2249 (48.0) | 2259 (48.4) | 4508 (48.2) |
| No | 2440 (52.0) | 2405 (51.6) | 4845 (51.8) |
| Body mass index (BMI) | | | |
| Underweight (<18.5 kg/m$^2$) | 53 (1.1) | 44 (0.9) | 97 (1.0) |
| Normal weight (≥18.5-24.9 kg/m$^2$) | 1333 (28.4) | 1358 (29.1) | 2691 (28.8) |
| Overweight (≥25.0-29.9 kg/m$^2$) | 1655 (35.3) | 1604 (34.4) | 3259 (34.8) |
| Obese (≥30.0 kg/m$^2$) | 1646 (35.1) | 1658 (35.5) | 3304 (35.3) |
| Missing | 2 (0.0) | 0 | 2 (0.0) |

a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
c. Number of participants who have 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least 1 Charlson Comorbidity Index category or a BMI ≥30 kg/m$^2$.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 16MAR2022 (08:50)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_demo_7d_eval_eff_new_nohiv

## 14.20. Concomitant Vaccines Received After Booster Vaccination – Safety Population

| Vaccine[b] | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055) n[c] (%) | Placebo (N[a]=5020) n[c] (%) |
| Any concomitant vaccines | 450 (8.9) | 891 (17.7) |
| COVID-19 VACCINE | 4 (0.1) | 8 (0.2) |
| COVID-19 VACCINE MRNA (MRNA 1273) | 4 (0.1) | 26 (0.5) |
| DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR 3-COMPONENT;TETANUS VACCINE TOXOID | 0 | 1 (0.0) |
| DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID | 4 (0.1) | 11 (0.2) |
| DIPHTHERIA VACCINE TOXOID;TETANUS VACCINE TOXOID | 7 (0.1) | 0 |
| DIPHTHERIA VACCINE;PERTUSSIS VACCINE;TETANUS VACCINE | 0 | 1 (0.0) |
| DIPHTHERIA VACCINE;TETANUS VACCINE | 0 | 2 (0.0) |
| HEPATITIS A VACCINE | 1 (0.0) | 2 (0.0) |
| HEPATITIS B VACCINE | 8 (0.2) | 6 (0.1) |
| HEPATITIS B VACCINE RHBSAG (YEAST) | 1 (0.0) | 0 |
| HEPATITIS VACCINES | 1 (0.0) | 1 (0.0) |
| HPV VACCINE | 1 (0.0) | 2 (0.0) |
| INFLUENZA VACCINE | 380 (7.5) | 591 (11.8) |
| INFLUENZA VACCINE INACT SAG 4V | 1 (0.0) | 2 (0.0) |
| INFLUENZA VACCINE INACT SPLIT 3V | 1 (0.0) | 13 (0.3) |
| INFLUENZA VACCINE INACT SPLIT 4V | 2 (0.0) | 14 (0.3) |
| INFLUENZA VACCINE RHA 4V (BACULOVIRUS) | 0 | 1 (0.0) |
| JNJ 78436735 | 1 (0.0) | 0 |
| MEASLES VACCINE;MUMPS VACCINE;RUBELLA VACCINE | 5 (0.1) | 4 (0.1) |
| MENINGOCOCCAL VACCINE A/C/Y/W CONJ (CRM197) | 0 | 1 (0.0) |
| MENINGOCOCCAL VACCINE B RFHBP/NADA/NHBA OMV | 0 | 1 (0.0) |
| PNEUMOCOCCAL VACCINE | 8 (0.2) | 4 (0.1) |
| PNEUMOCOCCAL VACCINE POLYSACCH 23V | 0 | 2 (0.0) |
| RABIES VACCINE | 1 (0.0) | 0 |
| RABIES VACCINE INACT (CHICK EMBRYO) | 0 | 1 (0.0) |
| RSV VACCINE | 2 (0.0) | 0 |
| TETANUS VACCINE | 4 (0.1) | 6 (0.1) |
| TOZINAMERAN | 30 (0.6) | 233 (4.6) |
| TYPHOID VACCINE | 1 (0.0) | 2 (0.0) |
| VARICELLA ZOSTER VACCINE | 16 (0.3) | 17 (0.3) |
| VARICELLA ZOSTER VACCINE LIVE (OKA/MERCK) | 0 | 1 (0.0) |
| VARICELLA ZOSTER VACCINE RGE (CHO) | 18 (0.4) | 11 (0.2) |
| YELLOW FEVER VACCINE | 3 (0.1) | 2 (0.0) |

## 14.20. Concomitant Vaccines Received After Booster Vaccination – Safety Population

| Vaccine[b] | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055) n[c] (%) | Placebo (N[a]=5020) n[c] (%) |

Note: WHODDG B3 v202103 coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. Participants are counted only once for each preferred term.
c. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adcm Table Generation: 15MAR2022 (06:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_fu_saf

## 14.21. Follow-Up Time After Booster Vaccination, by Age Group – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2823) n[b] (%) | Placebo (N[a]=2797) n[b] (%) | Total (N[a]=5620) n[b] (%) |
| Participants (%) with length of follow-up of: | | | |
| Blinded follow-up period | | | |
| <2 Months | 107 (3.8) | 152 (5.4) | 259 (4.6) |
| ≥2 Months to <4 months | 2183 (77.3) | 2401 (85.8) | 4584 (81.6) |
| ≥4 Months to <6 months | 229 (8.1) | 202 (7.2) | 431 (7.7) |
| ≥6 Months | 304 (10.8) | 42 (1.5) | 346 (6.2) |
| Mean (SD) | 3.4 (1.43) | 3.0 (0.87) | 3.2 (1.20) |
| Median | 3.0 | 2.9 | 2.9 |
| Min, max | (0.4, 7.5) | (0.3, 7.5) | (0.3, 7.5) |
| Total exposure from booster vaccination to the cutoff date | | | |
| <2 Months | 6 (0.2) | | |
| ≥2 Months to <4 months | 14 (0.5) | | |
| ≥4 Months to <6 months | 15 (0.5) | | |
| ≥6 Months | 2788 (98.8) | | |
| Mean (SD) | 7.0 (0.51) | | |
| Median | 7.0 | | |
| Min, max | (1.0, 8.0) | | |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
Note: Follow-up time for blinded period was calculated from booster vaccination to the cutoff date or withdrawal date or the day before date of unblinding (per protocol) or the day before date of receiving COVID-19 vaccine off study, whichever date was earlier.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 20MAR2022 (23:20)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File:
./nda2 ubBIA/C4591031 A SBLA/adsl fu d2 age saf

## 14.22. Follow-Up Time After Booster Vaccination, by Age Group – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2258) n[b] (%) | Placebo (N[a]=2247) n[b] (%) | Total (N[a]=4505) n[b] (%) |
| Participants (%) with length of follow-up of: | | | |
| Blinded follow-up period | | | |
| <2 Months | 46 (2.0) | 111 (4.9) | 157 (3.5) |
| ≥2 Months to <4 months | 1850 (81.9) | 1994 (88.7) | 3844 (85.3) |
| ≥4 Months to <6 months | 101 (4.5) | 124 (5.5) | 225 (5.0) |
| ≥6 Months | 261 (11.6) | 18 (0.8) | 279 (6.2) |
| Mean (SD) | 3.3 (1.47) | 2.8 (0.75) | 3.1 (1.19) |
| Median | 2.8 | 2.8 | 2.8 |
| Min, max | (0.8, 7.5) | (0.3, 7.4) | (0.3, 7.5) |
| Total exposure from booster vaccination to the cutoff date | | | |
| <2 Months | 3 (0.1) | | |
| ≥2 Months to <4 months | 11 (0.5) | | |
| ≥4 Months to <6 months | 7 (0.3) | | |
| ≥6 Months | 2237 (99.1) | | |
| Mean (SD) | 7.1 (0.45) | | |
| Median | 7.2 | | |
| Min, max | (1.0, 8.0) | | |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
Note: Follow-up time for blinded period was calculated from booster vaccination to the cutoff date or withdrawal date or the day before date of unblinding (per protocol) or the day before date of receiving COVID-19 vaccine off study, whichever date was earlier.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 20MAR2022 (23:20)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_fu_d2_age_saf

## 14.23. Follow-Up Time After BNT162b2 Booster Vaccination – Participants Who Originally Received Placebo – Safety Population

| | Vaccine Group (as Administered) |
|---|---|
| | BNT162b2 (30 µg) (N[a]=4419) n[b] (%) |
| Participants (%) with length of follow-up of: | |
| Open-label follow-up period | |
| <1 Month | 30 (0.7) |
| ≥1 Month to <2 months | 66 (1.5) |
| ≥2 Months to <3 months | 445 (10.1) |
| ≥3 Months to <4 months | 1877 (42.5) |
| ≥4 Months | 2001 (45.3) |
| Mean (SD) | 3.8 (0.73) |
| Median | 3.9 |
| Min, max | (0.2, 4.8) |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 20MAR2022 (23:02)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_fu_d2_pbo_saf

## 14.24. Follow-Up Time After Booster Vaccination – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5002) n[b] (%) | Placebo (N[a]=4966) n[b] (%) | Total (N[a]=9968) n[b] (%) |
| Participants (%) with length of follow-up of: | | | |
| Blinded follow-up period | | | |
| <2 Months | 147 (2.9) | 250 (5.0) | 397 (4.0) |
| ≥2 Months to <4 months | 3976 (79.5) | 4335 (87.3) | 8311 (83.4) |
| ≥4 Months to <6 months | 327 (6.5) | 322 (6.5) | 649 (6.5) |
| ≥6 Months | 552 (11.0) | 59 (1.2) | 611 (6.1) |
| Mean (SD) | 3.4 (1.44) | 2.9 (0.82) | 3.2 (1.19) |
| Median | 2.9 | 2.8 | 2.8 |
| Min, max | (0.4, 7.5) | (0.3, 7.5) | (0.3, 7.5) |
| Total exposure from booster vaccination to the cutoff date | | | |
| <2 Months | 9 (0.2) | | |
| ≥2 Months to <4 months | 24 (0.5) | | |
| ≥4 Months to <6 months | 19 (0.4) | | |
| ≥6 Months | 4950 (99.0) | | |
| Mean (SD) | 7.0 (0.48) | | |
| Median | 7.1 | | |
| Min, max | (1.0, 8.0) | | |

Note: Human immunodeficiency virus (HIV)-positive participants are included in this summary but not included in the analyses of the overall study objectives.
Note: Follow-up time for blinded period was calculated from booster vaccination to the cutoff date or withdrawal date or the day before date of unblinding (per protocol) or the day before date of receiving COVID-19 vaccine off study, whichever date was earlier.
a. N = number of participants in the specified group, or the total sample. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified characteristic.
PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: adsl Table Generation: 20MAR2022 (23:20)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsl_fu_d2_eval

## Efficacy

### 14.25. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – All-Available Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4755) | | Placebo (N[a]=4732) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First COVID-19 occurrence from 7 days after booster vaccination | 64 | 1.115 (4703) | 150 | 0.945 (4667) | 63.8 | (51.2, 73.4) |
| ≥7 Days after booster vaccination to <2 months after booster vaccination | 5 | 0.629 (4703) | 112 | 0.608 (4667) | 95.7 | (89.6, 98.6) |
| ≥2 Months after booster vaccination to <4 months after booster vaccination | 2 | 0.368 (4556) | 35 | 0.317 (4304) | 95.1 | (80.9, 99.4) |
| ≥4 Months after booster vaccination to <5 months after booster vaccination | 3 | 0.046 (779) | 0 | 0.013 (323) | UND | (NA, NA) |
| ≥5 Months after booster vaccination to <6 months after booster vaccination | 31 | 0.036 (514) | 2 | 0.004 (72) | -77.5 | (-1430.3, 54.8) |
| ≥6 Months after booster vaccination | 23 | 0.036 (446) | 1 | 0.003 (44) | -86.1 | (-7567.3, 69.8) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein-binding; NA = not applicable; NAAT = nucleic acid amplification test; RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster); SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; UND = undefined.
Note: Participants who had no serological or virological evidence (prior to 7 days after receipt of the booster vaccination) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visit 1, and had a negative NAAT [nasal swab] at any unscheduled visit prior to 7 days after booster vaccination) were included in the analysis.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period for the overall row and from the start to the end of the range stated for each time interval.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 22MAR2022 (10:31)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA_C4591031_A_SBLA/adc19ef_ve_cov_7d_wo_aai

## 14.26. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – All-Available Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5056) | | Placebo (N[a]=5019) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First COVID-19 occurrence from 7 days after booster vaccination | 68 | 1.192 (4979) | 152 | 1.003 (4920) | 62.4 | (49.6, 72.1) |
| ≥7 Days after booster vaccination to <2 months after booster vaccination | 6 | 0.665 (4979) | 113 | 0.642 (4920) | 94.9 | (88.5, 98.2) |
| ≥2 Months after booster vaccination to <4 months after booster vaccination | 2 | 0.396 (4825) | 35 | 0.340 (4550) | 95.1 | (80.9, 99.4) |
| ≥4 Months after booster vaccination to <5 months after booster vaccination | 4 | 0.050 (861) | 0 | 0.014 (351) | UND | (NA, NA) |
| ≥5 Months after booster vaccination to <6 months after booster vaccination | 32 | 0.040 (571) | 2 | 0.005 (79) | -81.0 | (-1458.6, 53.8) |
| ≥6 Months after booster vaccination | 24 | 0.040 (501) | 2 | 0.003 (48) | 5.9 | (-721.1, 76.6) |

Abbreviations: NA = not applicable; RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster); UND = undefined.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period for the overall row and from the start to the end of the range stated for each time interval.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 22MAR2022 (10:31)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_ve_cov_7d_aai

## 14.27. Signs and Symptoms of First COVID-19 Occurrence From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| Signs and Symptoms | BNT162b2 (30 µg) (N[a]=67) n[b](%) | Placebo (N[a]=150) n[b](%) | Total (N[a]=217) n[b](%) |
| Participants with specific signs and symptoms of COVID-19 | | | |
| Fever | 17 (25.4) | 68 (45.3) | 85 (39.2) |
| New or increased cough | 46 (68.7) | 106 (70.7) | 152 (70.0) |
| New or increased shortness of breath | 2 (3.0) | 20 (13.3) | 22 (10.1) |
| Chills | 28 (41.8) | 56 (37.3) | 84 (38.7) |
| New or increased muscle pain | 18 (26.9) | 69 (46.0) | 87 (40.1) |
| New loss of taste or smell | 6 (9.0) | 48 (32.0) | 54 (24.9) |
| Sore throat | 40 (59.7) | 58 (38.7) | 98 (45.2) |
| Diarrhea | 13 (19.4) | 26 (17.3) | 39 (18.0) |
| Vomiting | 4 (6.0) | 3 (2.0) | 7 (3.2) |
| Participants with specific number of signs and symptoms | | | |
| 1 | 15 (22.4) | 36 (24.0) | 51 (23.5) |
| 2 | 22 (32.8) | 29 (19.3) | 51 (23.5) |
| 3 | 18 (26.9) | 37 (24.7) | 55 (25.3) |
| 4 | 2 (3.0) | 16 (10.7) | 18 (8.3) |
| 5 | 7 (10.4) | 16 (10.7) | 23 (10.6) |
| >5 | 3 (4.5) | 16 (10.7) | 19 (8.8) |

a. N = number of participants with a first COVID-19 occurrence from 7 days after the booster vaccination in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified criteria meeting the COVID-19 case definition. A participant can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:12) Source Data: adc19ef Table Generation: 16MAR2022 (01:41)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsympt_symp_cov_7d_eval

## 14.28. Signs and Symptoms of First COVID-19 Occurrence After Booster Vaccination – Blinded Follow-Up Period – All-Available Efficacy Population

| | Vaccine Group (as Randomized) | | |
|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=76) | Placebo (N[a]=167) | Total (N[a]=243) |
| **Signs and Symptoms** | **n[b](%)** | **n[b](%)** | **n[b](%)** |
| Participants with specific signs and symptoms of COVID-19 | | | |
| Fever | 20 (26.3) | 71 (42.5) | 91 (37.4) |
| New or increased cough | 54 (71.1) | 116 (69.5) | 170 (70.0) |
| New or increased shortness of breath | 3 (3.9) | 24 (14.4) | 27 (11.1) |
| Chills | 31 (40.8) | 60 (35.9) | 91 (37.4) |
| New or increased muscle pain | 20 (26.3) | 79 (47.3) | 99 (40.7) |
| New loss of taste or smell | 10 (13.2) | 57 (34.1) | 67 (27.6) |
| Sore throat | 45 (59.2) | 63 (37.7) | 108 (44.4) |
| Diarrhea | 15 (19.7) | 27 (16.2) | 42 (17.3) |
| Vomiting | 5 (6.6) | 4 (2.4) | 9 (3.7) |
| Participants with specific number of signs and symptoms | | | |
| 1 | 16 (21.1) | 39 (23.4) | 55 (22.6) |
| 2 | 27 (35.5) | 33 (19.8) | 60 (24.7) |
| 3 | 19 (25.0) | 43 (25.7) | 62 (25.5) |
| 4 | 2 (2.6) | 18 (10.8) | 20 (8.2) |
| 5 | 7 (9.2) | 18 (10.8) | 25 (10.3) |
| >5 | 5 (6.6) | 16 (9.6) | 21 (8.6) |

a. N = number of participants with a first COVID-19 occurrence after the booster vaccination in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants with the specified criteria meeting the COVID-19 case definition. A participant can have more than 1 symptom.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:12) Source Data: adc19ef Table Generation: 16MAR2022 (01:41)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adsympt_symp_cov_aai

## 14.29. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination, by Subgroup – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4977) | | Placebo (N[a]=4942) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First COVID-19 occurrence from 7 days after booster vaccination | | | | | | |
| Overall | 67 | 1.173 (4903) | 150 | 0.989 (4846) | 62.4 | (49.5, 72.2) |
| Age group (years) | | | | | | |
| 16-55 | 38 | 0.656 (2716) | 97 | 0.561 (2691) | 66.5 | (50.8, 77.6) |
| >55 | 29 | 0.518 (2187) | 53 | 0.428 (2155) | 54.8 | (27.5, 72.3) |
| ≥65 | 8 | 0.260 (1144) | 17 | 0.221 (1140) | 60.0 | (2.3, 85.1) |
| 16-17 | 0 | 0.010 (45) | 2 | 0.008 (42) | 100.0 | (-331.2, 100.0) |
| 16-25 | 3 | 0.061 (247) | 8 | 0.058 (268) | 64.2 | (-49.2, 93.9) |
| 16-30 | 8 | 0.125 (500) | 14 | 0.111 (507) | 49.6 | (-28.9, 81.7) |
| 18-30 | 8 | 0.116 (455) | 12 | 0.103 (465) | 40.7 | (-57.6, 79.0) |
| 31-40 | 8 | 0.185 (764) | 35 | 0.157 (745) | 80.5 | (57.2, 92.2) |
| 16-40 | 16 | 0.310 (1264) | 49 | 0.268 (1252) | 71.7 | (49.5, 85.0) |
| 41-50 | 16 | 0.218 (922) | 26 | 0.194 (949) | 45.2 | (-6.1, 72.5) |
| 51-60 | 21 | 0.268 (1088) | 45 | 0.207 (1025) | 63.9 | (38.2, 79.6) |
| >60 | 14 | 0.377 (1629) | 30 | 0.319 (1620) | 60.5 | (23.2, 80.7) |
| 16-64 | 59 | 0.913 (3759) | 133 | 0.768 (3706) | 62.7 | (48.9, 73.0) |
| 18-64 | 59 | 0.904 (3714) | 131 | 0.760 (3664) | 62.1 | (48.1, 72.6) |
| 55-64 | 25 | 0.288 (1167) | 39 | 0.224 (1102) | 50.0 | (15.2, 71.0) |
| 65-74 | 7 | 0.201 (885) | 15 | 0.171 (887) | 60.2 | (-3.8, 86.3) |
| ≥75 | 1 | 0.059 (259) | 2 | 0.049 (253) | 58.3 | (-702.0, 99.3) |
| 75-85 | 1 | 0.059 (258) | 2 | 0.049 (249) | 58.7 | (-693.1, 99.3) |
| Sex | | | | | | |
| Male | 28 | 0.562 (2374) | 84 | 0.495 (2413) | 70.6 | (54.5, 81.6) |
| Female | 39 | 0.612 (2529) | 66 | 0.494 (2433) | 52.3 | (28.0, 68.7) |
| Race | | | | | | |
| White | 60 | 0.903 (3858) | 123 | 0.769 (3845) | 58.5 | (43.0, 70.0) |
| Black or African American | 1 | 0.123 (444) | 14 | 0.098 (430) | 94.3 | (62.7, 99.9) |
| American Indian or Alaska Native | 4 | 0.019 (82) | 6 | 0.017 (90) | 40.5 | (-150.9, 87.7) |
| Asian | 2 | 0.064 (280) | 3 | 0.051 (263) | 47.2 | (-361.2, 95.6) |
| Multiracial | 0 | 0.058 (208) | 3 | 0.050 (193) | 100.0 | (-106.9, 100.0) |
| Not reported | 0 | 0.005 (23) | 1 | 0.003 (14) | 100.0 | (-2198.3, 100.0) |

## 14.29. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination, by Subgroup – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4977) | | Placebo (N[a]=4942) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| Ethnicity | | | | | | |
| Hispanic/Latino | 19 | 0.181 (735) | 26 | 0.158 (731) | 36.2 | (-19.8, 66.6) |
| Non-Hispanic/non-Latino | 48 | 0.990 (4158) | 124 | 0.830 (4107) | 67.6 | (54.4, 77.3) |
| Country | | | | | | |
| Brazil | 0 | 0.151 (577) | 10 | 0.149 (578) | 100.0 | (56.2, 100.0) |
| South Africa | 3 | 0.037 (121) | 2 | 0.032 (127) | -26.3 | (-1412.2, 85.5) |
| USA | 64 | 0.985 (4205) | 138 | 0.809 (4141) | 61.9 | (48.4, 72.1) |
| Prior SARS-CoV-2 Status | | | | | | |
| Positive at baseline[f] | 4 | 0.075 (260) | 1 | 0.055 (238) | -194.9 | (-14421.3, 70.8) |
| Positive N-binding only | 3 | 0.066 (225) | 0 | 0.047 (198) | UND | (NA, NA) |
| Positive NAAT only | 1 | 0.002 (12) | 1 | 0.005 (23) | -106.4 | (-16102.8, 97.4) |
| Negative prior to 7 days after booster vaccination[g] | 63 | 1.098 (4637) | 148 | 0.932 (4600) | 63.8 | (51.1, 73.5) |
| Unknown | 0 | 0.001 (6) | 1 | 0.002 (8) | 100.0 | (-5647.4, 100.0) |
| Time between Dose 2 and booster vaccination | | | | | | |
| ≥6 to <8 Months after Dose 2 | 14 | 0.150 (723) | 11 | 0.125 (695) | -6.1 | (-158.2, 55.3) |
| ≥8 to <10 Months after Dose 2 | 5 | 0.192 (788) | 32 | 0.172 (786) | 86.0 | (63.9, 95.7) |
| ≥10 to <12 Months after Dose 2 | 43 | 0.791 (3221) | 101 | 0.662 (3196) | 64.4 | (48.6, 75.7) |
| ≥12 Months after Dose 2 | 5 | 0.041 (171) | 6 | 0.031 (169) | 36.8 | (-148.4, 84.8) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NA = not applicable; NAAT = nucleic acid amplification test; RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster); SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; UND = undefined.

a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
g. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and negative NAAT result at unscheduled visit, if any, prior to 7 days after booster vaccination.

PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 22MAR2022 (12:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_ve_cov_7d_sg_eval_new

## 14.30. Vaccine Efficacy – First COVID-19 Occurrence After Booster Vaccination by Subgroup – Blinded Follow-Up Period – All-Available Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5056) | | Placebo (N[a]=5019) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First COVID-19 occurrence after booster vaccination | | | | | | |
| Overall | 76 | 1.288 (4987) | 167 | 1.098 (4935) | 61.2 | (48.8, 70.8) |
| Age group (years) | | | | | | |
| 16-55 | 45 | 0.716 (2757) | 108 | 0.619 (2732) | 64.0 | (48.6, 75.2) |
| >55 | 31 | 0.572 (2230) | 59 | 0.479 (2203) | 56.0 | (30.9, 72.5) |
| ≥65 | 9 | 0.288 (1165) | 19 | 0.248 (1165) | 59.2 | (5.4, 83.8) |
| 16-17 | 0 | 0.011 (45) | 2 | 0.009 (43) | 100.0 | (-345.1, 100.0) |
| 16-25 | 3 | 0.066 (248) | 9 | 0.064 (271) | 67.8 | (-29.2, 94.4) |
| 16-30 | 9 | 0.137 (510) | 15 | 0.121 (510) | 47.2 | (-28.8, 79.6) |
| 18-30 | 9 | 0.127 (465) | 13 | 0.112 (467) | 38.8 | (-54.8, 76.9) |
| 31-40 | 11 | 0.200 (772) | 37 | 0.174 (756) | 74.2 | (48.3, 88.1) |
| 16-40 | 20 | 0.337 (1282) | 52 | 0.295 (1266) | 66.4 | (42.7, 81.0) |
| 41-50 | 19 | 0.239 (936) | 33 | 0.214 (965) | 48.4 | (6.5, 72.3) |
| 51-60 | 22 | 0.295 (1110) | 48 | 0.230 (1045) | 64.2 | (39.5, 79.4) |
| >60 | 15 | 0.417 (1659) | 34 | 0.358 (1659) | 62.1 | (28.5, 80.8) |
| 16-64 | 67 | 1.000 (3822) | 148 | 0.850 (3770) | 61.5 | (48.3, 71.6) |
| 18-64 | 67 | 0.989 (3777) | 146 | 0.841 (3727) | 61.0 | (47.5, 71.2) |
| 55-64 | 26 | 0.316 (1190) | 43 | 0.250 (1126) | 52.2 | (20.4, 71.8) |
| 65-74 | 8 | 0.223 (901) | 17 | 0.193 (907) | 59.3 | (0.5, 84.8) |
| ≥75 | 1 | 0.065 (264) | 2 | 0.055 (258) | 57.6 | (-713.8, 99.3) |
| 75-85 | 1 | 0.065 (262) | 2 | 0.054 (253) | 57.9 | (-708.2, 99.3) |
| Sex | | | | | | |
| Male | 34 | 0.616 (2412) | 94 | 0.549 (2459) | 67.7 | (51.7, 78.9) |
| Female | 42 | 0.672 (2575) | 73 | 0.548 (2476) | 53.1 | (30.5, 68.7) |
| Race | | | | | | |
| White | 67 | 0.993 (3928) | 137 | 0.856 (3921) | 57.8 | (43.1, 69.0) |
| Black or African American | 1 | 0.135 (452) | 15 | 0.108 (439) | 94.7 | (65.4, 99.9) |
| American Indian or Alaska Native | 4 | 0.021 (83) | 7 | 0.019 (90) | 48.5 | (-102.5, 88.9) |
| Asian | 4 | 0.071 (285) | 4 | 0.056 (266) | 20.1 | (-329.1, 85.1) |
| Multiracial | 0 | 0.062 (208) | 3 | 0.053 (194) | 100.0 | (-108.5, 100.0) |
| Not reported | 0 | 0.005 (23) | 1 | 0.003 (14) | 100.0 | (-2204.8, 100.0) |

## 14.30. Vaccine Efficacy – First COVID-19 Occurrence After Booster Vaccination, by Subgroup – Blinded Follow-Up Period – All-Available Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5056) | | Placebo (N[a]=5019) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| Ethnicity | | | | | | |
| Hispanic/Latino | 21 | 0.198 (747) | 28 | 0.175 (743) | 33.8 | (-20.8, 64.3) |
| Non-Hispanic/non-Latino | 55 | 1.088 (4229) | 139 | 0.922 (4184) | 66.5 | (53.9, 75.9) |
| Country | | | | | | |
| Brazil | 1 | 0.162 (578) | 10 | 0.160 (579) | 90.2 | (30.8, 99.8) |
| South Africa | 4 | 0.040 (123) | 2 | 0.034 (128) | -69.9 | (-1778.3, 75.6) |
| USA | 71 | 1.085 (4286) | 155 | 0.904 (4228) | 61.8 | (49.2, 71.6) |
| Baseline SARS-CoV-2 status | | | | | | |
| Positive[f] | 8 | 0.083 (280) | 7 | 0.062 (254) | 14.8 | (-176.1, 73.0) |
| Positive N-binding only | 3 | 0.073 (236) | 0 | 0.052 (205) | UND | (NA, NA) |
| Positive NAAT only | 5 | 0.003 (17) | 7 | 0.005 (30) | -40.4 | (-414.1, 64.9) |
| Negative[g] | 68 | 1.203 (4701) | 160 | 1.035 (4674) | 63.5 | (51.2, 72.9) |
| Time between Dose 2 and booster vaccination | | | | | | |
| ≥6 to <8 Months after Dose 2 | 13 | 0.167 (740) | 13 | 0.142 (714) | 1.9 | (-124.0, 56.5) |
| ≥8 to <10 Months after Dose 2 | 7 | 0.211 (801) | 36 | 0.190 (807) | 82.5 | (60.0, 93.4) |
| ≥10 to <12 Months after Dose 2 | 49 | 0.862 (3261) | 110 | 0.730 (3238) | 62.2 | (46.7, 73.6) |
| ≥12 Months after Dose 2 | 5 | 0.044 (171) | 8 | 0.034 (171) | 51.5 | (-68.1, 87.5) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NA = not applicable; NAAT = nucleic acid amplification test; RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster); SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2; UND = undefined.

a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from the booster vaccination to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
g. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.

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(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_ve_cov_sg_aai_new

## 14.31. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination, by Risk Status – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4977) | | Placebo (N[a]=4942) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First COVID-19 occurrence from 7 days after booster vaccination | | | | | | |
| Overall | 67 | 1.173 (4903) | 150 | 0.989 (4846) | 62.4 | (49.5, 72.2) |
| At risk[f] | | | | | | |
| Yes | 37 | 0.566 (2350) | 75 | 0.475 (2344) | 58.6 | (37.8, 72.9) |
| No | 30 | 0.608 (2553) | 75 | 0.514 (2502) | 66.2 | (47.7, 78.6) |
| Age group (years) and at risk status | | | | | | |
| 16-64 and not at risk | 24 | 0.497 (2063) | 63 | 0.415 (1988) | 68.2 | (48.3, 81.0) |
| 16-64 and at risk | 35 | 0.416 (1696) | 70 | 0.353 (1718) | 57.7 | (35.6, 72.6) |
| ≥65 and not at risk | 6 | 0.111 (490) | 12 | 0.099 (514) | 55.4 | (-28.5, 86.3) |
| ≥65 and at risk | 2 | 0.149 (654) | 5 | 0.122 (626) | 67.3 | (-99.7, 96.9) |
| Obese[g] | | | | | | |
| Yes | 25 | 0.424 (1734) | 60 | 0.354 (1726) | 65.2 | (43.6, 79.1) |
| No | 42 | 0.749 (3167) | 90 | 0.635 (3120) | 60.5 | (42.4, 73.3) |
| Age group (years) and obesity status | | | | | | |
| 16-64 and not obese | 35 | 0.580 (2410) | 77 | 0.488 (2352) | 61.8 | (42.3, 75.1) |
| 16-64 and obese | 24 | 0.334 (1348) | 56 | 0.280 (1354) | 64.0 | (40.9, 78.6) |
| ≥65 and not obese | 7 | 0.170 (757) | 13 | 0.147 (768) | 53.4 | (-25.8, 84.2) |
| ≥65 and obese | 1 | 0.090 (386) | 4 | 0.074 (372) | 79.5 | (-107.1, 99.6) |

Abbreviation: RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster).
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. 2-sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Includes participants who had at least 1 Charlson Comorbidity Index category or a BMI ≥30 kg/m$^2$.
g. Participants who had a BMI ≥30 kg/m$^2$.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 16MAR2022 (01:41)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_ve_cov_7d_rg_eval

## 14.32. Vaccine Efficacy – First COVID-19 Occurrence From 7 Days After Booster Vaccination, by Comorbidity Status – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4977) | | Placebo (N[a]=4942) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First COVID-19 occurrence from 7 days after booster vaccination | | | | | | |
| Overall | 67 | 1.173 (4903) | 150 | 0.989 (4846) | 62.4 | (49.5, 72.2) |
| Comorbidity | | | | | | |
| No comorbidity | 30 | 0.608 (2553) | 75 | 0.514 (2502) | 66.2 | (47.7, 78.6) |
| Any comorbidity[f] | 37 | 0.566 (2350) | 75 | 0.475 (2344) | 58.6 | (37.8, 72.9) |
| Any malignancy | 4 | 0.056 (252) | 5 | 0.043 (223) | 37.6 | (-189.9, 87.6) |
| Cardiovascular | 3 | 0.038 (176) | 1 | 0.027 (141) | -114.0 | (-11134.2, 82.8) |
| Chronic pulmonary disease | 7 | 0.103 (430) | 17 | 0.089 (456) | 64.3 | (9.3, 87.5) |
| Diabetes | 8 | 0.102 (407) | 17 | 0.079 (400) | 63.3 | (10.3, 86.3) |
| Obese (≥30.0 kg/m$^2$) | 25 | 0.424 (1734) | 60 | 0.354 (1726) | 65.2 | (43.6, 79.1) |
| Hypertension | 17 | 0.320 (1336) | 39 | 0.266 (1321) | 63.8 | (34.5, 80.8) |
| Diabetes (including gestational diabetes) | 8 | 0.103 (410) | 17 | 0.080 (403) | 63.3 | (10.3, 86.3) |

Abbreviation: RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster).
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
f. Participant who had 1 or more comorbidities that increase the risk of severe COVID-19 disease: defined as participants who had at least 1 Charlson Comorbidity Index category or a BMI ≥30 kg/m$^2$.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 16MAR2022 (01:41)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBA/C4591031_A_SBLA/adc19ef_ve_cov_7d_cg_eval

## 14.33. Vaccine Efficacy – First Severe COVID-19 Occurrence (Based on FDA Definition) From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4689) | | Placebo (N[a]=4664) | | | |
| Efficacy Endpoint | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First severe COVID-19 occurrence (based on FDA definition) from 7 days after booster vaccination | 0 | 1.105 (4639) | 2 | 0.951 (4601) | 100.0 | (-358.6, 100.0) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster); SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants who had no serological or virological evidence (prior to 7 days after receipt of the booster vaccination) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visit 1, and had a negative NAAT [nasal swab] at any unscheduled visit prior to 7 days after booster vaccination) were included in the analysis.
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 16MAR2022 (01:41)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_ve_sev_fda_7d_wo_eval

## 14.34. Vaccine Efficacy – First Severe COVID-19 Occurrence (Based on FDA Definition) From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – Evaluable Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4977) | | Placebo (N[a]=4942) | | | |
| Efficacy Endpoint | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First severe COVID-19 occurrence (based on FDA definition) from 7 days after booster vaccination | 0 | 1.182 (4911) | 2 | 1.011 (4861) | 100.0 | (-355.5, 100.0) |

Abbreviation: RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster).
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 16MAR2022 (01:41)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_ve_sev_fda_7d_eval

## 14.35. Vaccine Efficacy – First Severe COVID-19 Occurrence (Based on FDA Definition) From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants Without Evidence of Infection Prior to 7 Days After Booster Vaccination – All-Available Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4755) | | Placebo (N[a]=4732) | | | |
| Efficacy Endpoint | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First severe COVID-19 occurrence (based on FDA definition) from 7 days after booster vaccination | 0 | 1.121 (4703) | 3 | 0.966 (4667) | 100.0 | (-108.5, 100.0) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster); SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.

Note: Participants who had no serological or virological evidence (prior to 7 days after receipt of the booster vaccination) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visit 1, and had a negative NAAT [nasal swab] at any unscheduled visit prior to 7 days after booster vaccination) were included in the analysis.

a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.

PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 16MAR2022 (01:41)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_ve_sev_fda_7d_wo_aai

## 14.36. Vaccine Efficacy – First Severe COVID-19 Occurrence (Based on FDA Definition) From 7 Days After Booster Vaccination – Blinded Follow-Up Period – Participants With or Without Evidence of Infection Prior to 7 Days After Booster Vaccination – All-Available Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5056) | | Placebo (N[a]=5019) | | | |
| Efficacy Endpoint | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First severe COVID-19 occurrence (based on FDA definition) from 7 days after booster vaccination | 0 | 1.201 (4987) | 3 | 1.027 (4935) | 100.0 | (-107.0, 100.0) |

Abbreviation: RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster).
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after the booster vaccination to the end of the surveillance period.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 16MAR2022 (01:41)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_ve_sev_fda_7d_aai

## 14.37. Vaccine Efficacy – First Severe COVID-19 Occurrence (Based on FDA Definition) After Booster Vaccination – Blinded Follow-Up Period – All-Available Efficacy Population

| | Vaccine Group (as Randomized) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5056) | | Placebo (N[a]=5019) | | | |
| Efficacy Endpoint Subgroup | n1[b] | Surveillance Time[c] (n2[d]) | n1[b] | Surveillance Time[c] (n2[d]) | RVE (%) | (95% CI[e]) |
| First severe COVID-19 occurrence (based on FDA definition) after booster vaccination | 0 | 1.297 (4987) | 3 | 1.122 (4935) | 100.0 | (-109.4, 100.0) |
| Booster vaccination to 7 days after booster vaccination | 0 | 0.096 (4987) | 0 | 0.095 (4935) | NE | |
| ≥7 days after booster vaccination | 0 | 1.201 (4987) | 3 | 1.027 (4935) | 100.0 | (-107.0, 100.0) |

Abbreviations: NE = not estimable; RVE = relative vaccine efficacy of the BNT162b2 booster group relative to the placebo group (nonbooster).
a. N = number of participants in the specified group.
b. n1 = Number of participants meeting the endpoint definition.
c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from the booster vaccination to the end of the surveillance period for the overall row and from the start to the end of the range stated for each time interval.
d. n2 = Number of participants at risk for the endpoint.
e. 2-Sided CI for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19ef Table Generation: 16MAR2022 (01:41)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adc19ef_vc_sev_cov_fda_aai

## 14.38. Relative Vaccine Efficacy – First COVID-19 Occurrence After BNT162b2 Booster Vaccination From 27SEP2021 to 08FEB2022 – Participants Who Received BNT162b2 Booster Vaccination – All-Available Efficacy Population

| | Vaccine Group | | | | | |
|---|---|---|---|---|---|---|
| | Placebo Crossover to BNT162b2 (30 µg) | | Original BNT162b2 (30 µg) | | | |
| Efficacy Endpoint | n1[a] | Surveillance Time[b] (n2[c]) | n1[a] | Surveillance Time[b] (n2[c]) | RVE (%) | (95% CI[d]) |
| First COVID-19 occurrence from 27SEP2021[e] to 19DEC2021 | 20 | 0.642 (4218) | 42 | 1.101 (4817) | 18.3 | (-42.3, 54.6) |
| First COVID-19 occurrence from 20DEC2021[f] to 08FEB2022[g] | 323 | 0.560 (4254) | 603 | 0.609 (4739) | 41.8 | (33.2, 49.3) |

Abbreviation: RVE = crossover efficacy relative to the original BNT162b2 efficacy.
Note: Participants who received BNT162b2 booster vaccination and remained at risk until at least 27SEP2021 or 20DEC2021 were included in the analysis.
a. n1 = Number of participants meeting the endpoint definition.
b. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from latest of BNT162b2 booster vaccination and 27SEP2021 (first row) or 20DEC2021 (second row) to the earliest of confirmed case, death, withdrawn from the study, or 19DEC2021 (first row) or 08FEB2022 (second row).
c. n2 = Number of participants at risk for the endpoint.
d. Confidence interval (CI) for RVE is derived based on the Clopper and Pearson method adjusted for surveillance time.
e. Date of the first placebo crossover participants receiving BNT162b2 vaccination.
f. Approximate date of Omicron being the predominant strain.
g. Data cutoff date of this analysis.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19eu Table Generation: 16MAR2022 (10:49)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 18FEB2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA_RVE/adc19ef_rve_cov_bnt_aai

## 14.39. Incidence Rates of First COVID-19 Occurrence After BNT162b2 Booster Vaccination – Participants Who Received BNT162b2 Booster Vaccination – All-Available Efficacy Population

| | Vaccine Group | | | | | |
|---|---|---|---|---|---|---|
| | Placebo Crossover to BNT162b2 (30 µg) | | | Original BNT162b2 (30 µg) | | |
| Efficacy Endpoint | n1[a] | Surveillance Time[b] (n2[c]) | IR (/1000 PY)[d] | n1[a] | Surveillance Time[b] (n2[c]) | IR (/1000 PY)[d] |
| First COVID-19 occurrence after booster vaccination | 343 | 1.202 (4283) | 285.393 | 659 | 2.551 (4840) | 258.361 |
| First COVID-19 occurrence from 27SEP2021[e] to 19DEC2021 | 20 | 0.642 (4218) | 31.159 | 42 | 1.101 (4817) | 38.136 |
| First COVID-19 occurrence from 20DEC2021[f] to 08FEB2022[g] | 323 | 0.560 (4254) | 576.808 | 603 | 0.609 (4739) | 990.327 |

a. n1 = Number of participants meeting the endpoint definition.
b. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from latest of BNT162b2 booster vaccination date and 27SEP2021 (second row) or 20DEC2021 (third row) to the earliest of confirmed case, death, withdrawn from the study, or 19DEC2021 (second row) or 08FEB2022 (third row). Time period for COVID-19 case accrual for the first row is from the BNT162b2 booster vaccination to the end of the surveillance period.
c. n2 = Number of participants at risk for the endpoint.
d. Incidence rate (IR) is calculated as number of participants meeting the endpoint definition/total surveillance time across all participants at risk for the endpoint within the specific group.
e. Date of the first placebo crossover participants receiving BNT162b2 vaccination.
f. Approximate date of Omicron being the predominant strain.
g. Data cutoff date of this analysis.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19eu Table Generation: 16MAR2022 (06:04)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 18FEB2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA_RVE/adc19ef_ir_cov_bnt_aai

## 14.40. Incidence Rates of First COVID-19 Occurrence After BNT162b2 Booster Vaccination From 20DEC2021 to 08FEB2022 by Time Since BNT162b2 Booster Vaccination – Participants Who Received BNT162b2 Booster Vaccination – All-Available Efficacy Population

| | Vaccine Group | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Placebo Crossover to BNT162b2 (30 µg) | | | Original BNT162b2 (30 µg) | | | Total | | |
| Efficacy Endpoint | n1[a] | Surveillance Time[b] (n2[c]) | IR (/1000 PY)[d] | n1[a] | Surveillance Time[b] (n2[c]) | IR (/1000 PY)[d] | n1[a] | Surveillance Time[b] (n2[c]) | IR (/1000 PY)[d] |
| First COVID-19 occurrence from 20DEC2021[e] to 08FEB2022[f] | 323 | 0.560 (4254) | 576.808 | 603 | 0.609 (4739) | 990.327 | 926 | 1.169 (8993) | 792.220 |
| Time from BNT162b2 booster vaccination to 20DEC2021[e] | | | | | | | | | |
| <1 Months | 16 | 0.046 (360) | 349.146 | - | - (0) | - | 16 | 0.046 (360) | 349.146 |
| ≥1-<2 Months | 143 | 0.196 (1481) | 729.979 | - | - (0) | - | 143 | 0.196 (1481) | 729.979 |
| ≥2-<3 Months | 159 | 0.312 (2362) | 510.157 | - | - (0) | - | 159 | 0.312 (2362) | 510.157 |
| ≥3-<4 Months | 5 | 0.007 (51) | 759.040 | - | - (0) | - | 5 | 0.007 (51) | 759.040 |
| ≥4-<5 Months | - | - (0) | - | 80 | 0.089 (695) | 900.435 | 80 | 0.089 (695) | 900.435 |
| ≥5-<6 Months | - | - (0) | - | 523 | 0.519 (4036) | 1007.85 | 523 | 0.519 (4036) | 1007.85 |
| ≥6-<7 Months | - | - (0) | - | 0 | 0.001 (8) | 0.000 | 0 | 0.001 (8) | 0.000 |

Note: Participants who received BNT162b2 booster vaccination and remained at risk until at least 20DEC2021 were included in the analysis.
a. n1 = Number of participants meeting the endpoint definition.
b. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 20DEC2021 to the earliest of confirmed case, death, withdrawn from the study, or 08FEB2022.
c. n2 = Number of participants at risk for the endpoint.
d. Incidence rate (IR) is calculated as number of participants meeting the endpoint definition/total surveillance time across all participants at risk for the endpoint within the specific group.
e. Approximate date of Omicron being the predominant strain.
f. Data cutoff date of this analysis.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adc19eu Table Generation: 21MAR2022 (22:08)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 18FEB2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA_RVE/adc19ef_ir_time_cov_bnt_aai

## Adverse Events

### 14.41. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 803 | 28.6 (27.0, 30.4) | 110.1 | (102.6, 118.0) | 219 | 7.9 (6.9, 8.9) | 34.2 | (29.8, 39.1) |
| Related[g] | 753 | 26.9 (25.2, 28.5) | 103.2 | (96.0, 110.9) | 127 | 4.6 (3.8, 5.4) | 19.9 | (16.5, 23.6) |
| Severe | 24 | 0.9 (0.5, 1.3) | 3.3 | (2.1, 4.9) | 16 | 0.6 (0.3, 0.9) | 2.5 | (1.4, 4.1) |
| Life-threatening | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Any serious adverse event | 15 | 0.5 (0.3, 0.9) | 2.1 | (1.2, 3.4) | 14 | 0.5 (0.3, 0.8) | 2.2 | (1.2, 3.7) |
| Related[g] | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Severe | 9 | 0.3 (0.1, 0.6) | 1.2 | (0.6, 2.3) | 12 | 0.4 (0.2, 0.8) | 1.9 | (1.0, 3.3) |
| Life-threatening | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Any nonserious adverse event | 797 | 28.4 (26.8, 30.1) | 109.3 | (101.8, 117.1) | 214 | 7.7 (6.7, 8.7) | 33.4 | (29.1, 38.2) |
| Related[g] | 752 | 26.8 (25.2, 28.5) | 103.1 | (95.9, 110.7) | 127 | 4.6 (3.8, 5.4) | 19.9 | (16.5, 23.6) |
| Severe | 16 | 0.6 (0.3, 0.9) | 2.2 | (1.3, 3.6) | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Severe | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Death | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (20:28)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s092_age_6m_saf

## 14.42. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 532 | 23.6 (21.9, 25.4) | 92.5 | (84.8, 100.7) | 175 | 7.8 (6.7, 9.0) | 35.8 | (30.7, 41.5) |
| Related[g] | 453 | 20.1 (18.5, 21.8) | 78.8 | (71.7, 86.4) | 86 | 3.8 (3.1, 4.7) | 17.6 | (14.1, 21.7) |
| Severe | 31 | 1.4 (0.9, 1.9) | 5.4 | (3.7, 7.7) | 18 | 0.8 (0.5, 1.3) | 3.7 | (2.2, 5.8) |
| Life-threatening | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Any serious adverse event | 24 | 1.1 (0.7, 1.6) | 4.2 | (2.7, 6.2) | 21 | 0.9 (0.6, 1.4) | 4.3 | (2.7, 6.6) |
| Related[g] | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Severe | 14 | 0.6 (0.3, 1.0) | 2.4 | (1.3, 4.1) | 14 | 0.6 (0.3, 1.0) | 2.9 | (1.6, 4.8) |
| Life-threatening | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Any nonserious adverse event | 516 | 22.9 (21.2, 24.7) | 89.7 | (82.2, 97.8) | 163 | 7.3 (6.2, 8.4) | 33.3 | (28.4, 38.9) |
| Related[g] | 452 | 20.1 (18.4, 21.8) | 78.6 | (71.5, 86.2) | 86 | 3.8 (3.1, 4.7) | 17.6 | (14.1, 21.7) |
| Severe | 20 | 0.9 (0.5, 1.4) | 3.5 | (2.1, 5.4) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Life-threatening | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Related[g] | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Severe | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Life-threatening | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Death | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
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## 14.43. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex – Blinded Follow-Up Period – Safety Population Sex: Male

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2443, TE[b]=6.2) | | | | Placebo (N[a]=2500, TE[b]=5.7) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 568 | 23.3 (21.6, 25.0) | 91.1 | (83.7, 98.9) | 158 | 6.3 (5.4, 7.3) | 27.9 | (23.7, 32.6) |
| Related[g] | 506 | 20.7 (19.1, 22.4) | 81.1 | (74.2, 88.5) | 93 | 3.7 (3.0, 4.5) | 16.4 | (13.2, 20.1) |
| Severe | 22 | 0.9 (0.6, 1.4) | 3.5 | (2.2, 5.3) | 18 | 0.7 (0.4, 1.1) | 3.2 | (1.9, 5.0) |
| Life-threatening | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Any serious adverse event | 21 | 0.9 (0.5, 1.3) | 3.4 | (2.1, 5.1) | 19 | 0.8 (0.5, 1.2) | 3.4 | (2.0, 5.2) |
| Related[g] | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Severe | 12 | 0.5 (0.3, 0.9) | 1.9 | (1.0, 3.4) | 14 | 0.6 (0.3, 0.9) | 2.5 | (1.4, 4.1) |
| Life-threatening | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Any nonserious adverse event | 557 | 22.8 (21.1, 24.5) | 89.3 | (82.0, 97.0) | 150 | 6.0 (5.1, 7.0) | 26.5 | (22.4, 31.1) |
| Related[g] | 506 | 20.7 (19.1, 22.4) | 81.1 | (74.2, 88.5) | 93 | 3.7 (3.0, 4.5) | 16.4 | (13.2, 20.1) |
| Severe | 13 | 0.5 (0.3, 0.9) | 2.1 | (1.1, 3.6) | 6 | 0.2 (0.1, 0.5) | 1.1 | (0.4, 2.3) |
| Life-threatening | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Related[g] | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Severe | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Life-threatening | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Death | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
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## 14.44. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | | Placebo (N[a]=2520, TE[b]=5.6) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 767 | 29.4 (27.6, 31.2) | 112.7 | (104.9, 121.0) | 236 | 9.4 (8.3, 10.6) | 42.0 | (36.8, 47.7) |
| Related[g] | 700 | 26.8 (25.1, 28.5) | 102.8 | (95.4, 110.8) | 120 | 4.8 (4.0, 5.7) | 21.4 | (17.7, 25.5) |
| Severe | 33 | 1.3 (0.9, 1.8) | 4.8 | (3.3, 6.8) | 16 | 0.6 (0.4, 1.0) | 2.8 | (1.6, 4.6) |
| Life-threatening | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Any serious adverse event | 18 | 0.7 (0.4, 1.1) | 2.6 | (1.6, 4.2) | 16 | 0.6 (0.4, 1.0) | 2.8 | (1.6, 4.6) |
| Related[g] | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Severe | 11 | 0.4 (0.2, 0.8) | 1.6 | (0.8, 2.9) | 12 | 0.5 (0.2, 0.8) | 2.1 | (1.1, 3.7) |
| Life-threatening | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Any nonserious adverse event | 756 | 28.9 (27.2, 30.7) | 111.1 | (103.3, 119.3) | 227 | 9.0 (7.9, 10.2) | 40.4 | (35.3, 46.0) |
| Related[g] | 698 | 26.7 (25.0, 28.5) | 102.6 | (95.1, 110.5) | 120 | 4.8 (4.0, 5.7) | 21.4 | (17.7, 25.5) |
| Severe | 23 | 0.9 (0.6, 1.3) | 3.4 | (2.1, 5.1) | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.1) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Severe | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Death | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
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## 14.45. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| Adverse Event | n[c] (%) | % (95% CI[d]) | IR (/100 PY[e]) | 95% CI[f] | n[c] (%) | % (95% CI[d]) | IR (/100 PY[e]) | 95% CI[f] |
| Any event | 996 | 25.0 (23.6, 26.4) | 98.9 | (92.8, 105.2) | 303 | 7.6 (6.8, 8.5) | 34.4 | (30.6, 38.4) |
| Related[g] | 887 | 22.3 (21.0, 23.6) | 88.1 | (82.4, 94.0) | 149 | 3.7 (3.2, 4.4) | 16.9 | (14.3, 19.8) |
| Severe | 46 | 1.2 (0.8, 1.5) | 4.6 | (3.3, 6.1) | 28 | 0.7 (0.5, 1.0) | 3.2 | (2.1, 4.6) |
| Life-threatening | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 4 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.2) |
| Any serious adverse event | 34 | 0.9 (0.6, 1.2) | 3.4 | (2.3, 4.7) | 28 | 0.7 (0.5, 1.0) | 3.2 | (2.1, 4.6) |
| Related[g] | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Severe | 19 | 0.5 (0.3, 0.7) | 1.9 | (1.1, 2.9) | 22 | 0.6 (0.3, 0.8) | 2.5 | (1.6, 3.8) |
| Life-threatening | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 4 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.2) |
| Any nonserious adverse event | 975 | 24.5 (23.1, 25.8) | 96.8 | (90.8, 103.1) | 290 | 7.3 (6.5, 8.1) | 32.9 | (29.2, 36.9) |
| Related[g] | 885 | 22.2 (20.9, 23.5) | 87.9 | (82.2, 93.8) | 149 | 3.7 (3.2, 4.4) | 16.9 | (14.3, 19.8) |
| Severe | 31 | 0.8 (0.5, 1.1) | 3.1 | (2.1, 4.4) | 8 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.8) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Severe | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Death | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.

b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.

c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.

d. 2-Sided CI based on Clopper-Pearson.

e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.

f. 2-Sided CI based on Poisson distribution.

g. Assessed by the investigator as related to study intervention.

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## 14.46. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race – Blinded Follow-Up Period – Safety Population Race: Black or African American

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=457, TE[b]=1.4) | | | | Placebo (N[a]=447, TE[b]=1.1) | | | |
| Adverse Event | n[c] (%) | % (95% CI[d]) | IR (/100 PY[e]) | 95% CI[f] | n[c] (%) | % (95% CI[d]) | IR (/100 PY[e]) | 95% CI[f] |
| Any event | 115 | 25.2 (21.2, 29.4) | 84.8 | (70.0, 101.8) | 36 | 8.1 (5.7, 11.0) | 32.5 | (22.8, 45.1) |
| Related[g] | 105 | 23.0 (19.2, 27.1) | 77.4 | (63.3, 93.7) | 23 | 5.1 (3.3, 7.6) | 20.8 | (13.2, 31.2) |
| Severe | 3 | 0.7 (0.1, 1.9) | 2.2 | (0.5, 6.5) | 2 | 0.4 (0.1, 1.6) | 1.8 | (0.2, 6.5) |
| Life-threatening | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Any serious adverse event | 2 | 0.4 (0.1, 1.6) | 1.5 | (0.2, 5.3) | 3 | 0.7 (0.1, 1.9) | 2.7 | (0.6, 7.9) |
| Related[g] | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Severe | 2 | 0.4 (0.1, 1.6) | 1.5 | (0.2, 5.3) | 2 | 0.4 (0.1, 1.6) | 1.8 | (0.2, 6.5) |
| Life-threatening | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Any nonserious adverse event | 114 | 24.9 (21.0, 29.2) | 84.1 | (69.4, 101.0) | 33 | 7.4 (5.1, 10.2) | 29.8 | (20.5, 41.9) |
| Related[g] | 105 | 23.0 (19.2, 27.1) | 77.4 | (63.3, 93.7) | 23 | 5.1 (3.3, 7.6) | 20.8 | (13.2, 31.2) |
| Severe | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Life-threatening | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Related[g] | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Severe | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Life-threatening | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Death | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |

Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
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## 14.47. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race – Blinded Follow-Up Period – Safety Population Race: All Others

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=612, TE[b]=1.6) | | | | Placebo (N[a]=580, TE[b]=1.4) | | | |
| Adverse Event | n[c] (%) | % (95% CI[d]) | IR (/100 PY[e]) | 95% CI[f] | n[c] (%) | % (95% CI[d]) | IR (/100 PY[e]) | 95% CI[f] |
| Any event | 224 | 36.6 (32.8, 40.6) | 138.7 | (121.1, 158.1) | 55 | 9.5 (7.2, 12.2) | 40.4 | (30.4, 52.5) |
| Related[g] | 214 | 35.0 (31.2, 38.9) | 132.5 | (115.3, 151.5) | 41 | 7.1 (5.1, 9.5) | 30.1 | (21.6, 40.8) |
| Severe | 6 | 1.0 (0.4, 2.1) | 3.7 | (1.4, 8.1) | 4 | 0.7 (0.2, 1.8) | 2.9 | (0.8, 7.5) |
| Life-threatening | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Any serious adverse event | 3 | 0.5 (0.1, 1.4) | 1.9 | (0.4, 5.4) | 4 | 0.7 (0.2, 1.8) | 2.9 | (0.8, 7.5) |
| Related[g] | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Severe | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 2 | 0.3 (0.0, 1.2) | 1.5 | (0.2, 5.3) |
| Life-threatening | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Any nonserious adverse event | 224 | 36.6 (32.8, 40.6) | 138.7 | (121.1, 158.1) | 54 | 9.3 (7.1, 12.0) | 39.6 | (29.8, 51.7) |
| Related[g] | 214 | 35.0 (31.2, 38.9) | 132.5 | (115.3, 151.5) | 41 | 7.1 (5.1, 9.5) | 30.1 | (21.6, 40.8) |
| Severe | 4 | 0.7 (0.2, 1.7) | 2.5 | (0.7, 6.3) | 3 | 0.5 (0.1, 1.5) | 2.2 | (0.5, 6.4) |
| Life-threatening | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Related[g] | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Severe | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Life-threatening | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Death | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |

Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
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## 14.48. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity – Blinded Follow-Up Period – Safety Population Ethnicity: Hispanic/Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=757, TE[b]=2.0) | | | | Placebo (N[a]=749, TE[b]=1.8) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 282 | 37.3 (33.8, 40.8) | 140.1 | (124.2, 157.5) | 74 | 9.9 (7.8, 12.2) | 41.5 | (32.6, 52.0) |
| Related[g] | 271 | 35.8 (32.4, 39.3) | 134.7 | (119.1, 151.7) | 50 | 6.7 (5.0, 8.7) | 28.0 | (20.8, 36.9) |
| Severe | 2 | 0.3 (0.0, 1.0) | 1.0 | (0.1, 3.6) | 6 | 0.8 (0.3, 1.7) | 3.4 | (1.2, 7.3) |
| Life-threatening | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Any serious adverse event | 3 | 0.4 (0.1, 1.2) | 1.5 | (0.3, 4.4) | 6 | 0.8 (0.3, 1.7) | 3.4 | (1.2, 7.3) |
| Related[g] | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Severe | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 4 | 0.5 (0.1, 1.4) | 2.2 | (0.6, 5.7) |
| Life-threatening | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Any nonserious adverse event | 281 | 37.1 (33.7, 40.7) | 139.6 | (123.8, 156.9) | 72 | 9.6 (7.6, 12.0) | 40.3 | (31.6, 50.8) |
| Related[g] | 271 | 35.8 (32.4, 39.3) | 134.7 | (119.1, 151.7) | 50 | 6.7 (5.0, 8.7) | 28.0 | (20.8, 36.9) |
| Severe | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 2 | 0.3 (0.0, 1.0) | 1.1 | (0.1, 4.0) |
| Life-threatening | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Related[g] | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Severe | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Life-threatening | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Death | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
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## 14.49. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 1050 | 24.5 (23.2, 25.8) | 95.4 | (89.7, 101.3) | 320 | 7.5 (6.7, 8.3) | 33.7 | (30.1, 37.6) |
| Related[g] | 932 | 21.7 (20.5, 23.0) | 84.7 | (79.3, 90.3) | 163 | 3.8 (3.3, 4.4) | 17.2 | (14.6, 20.0) |
| Severe | 53 | 1.2 (0.9, 1.6) | 4.8 | (3.6, 6.3) | 28 | 0.7 (0.4, 0.9) | 3.0 | (2.0, 4.3) |
| Life-threatening | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) |
| Any serious adverse event | 36 | 0.8 (0.6, 1.2) | 3.3 | (2.3, 4.5) | 29 | 0.7 (0.5, 1.0) | 3.1 | (2.0, 4.4) |
| Related[g] | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Severe | 22 | 0.5 (0.3, 0.8) | 2.0 | (1.3, 3.0) | 22 | 0.5 (0.3, 0.8) | 2.3 | (1.5, 3.5) |
| Life-threatening | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) |
| Any nonserious adverse event | 1029 | 24.0 (22.7, 25.3) | 93.5 | (87.9, 99.4) | 305 | 7.2 (6.4, 8.0) | 32.1 | (28.6, 36.0) |
| Related[g] | 930 | 21.7 (20.5, 23.0) | 84.5 | (79.1, 90.1) | 163 | 3.8 (3.3, 4.4) | 17.2 | (14.6, 20.0) |
| Severe | 35 | 0.8 (0.6, 1.1) | 3.2 | (2.2, 4.4) | 9 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.8) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Severe | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Death | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (20:43)
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## 14.50. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity – Blinded Follow-Up Period – Safety Population Ethnicity: Not Reported

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=12, TE[b]=0.0) | | | | Placebo (N[a]=8, TE[b]=0.0) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 3 | 25.0 (5.5, 57.2) | 121.8 | (25.1, 355.8) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Related[g] | 3 | 25.0 (5.5, 57.2) | 121.8 | (25.1, 355.8) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Severe | 0 | 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Life-threatening | 0 | 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Any serious adverse event | 0 | 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Related[g] | 0 | 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Severe | 0 | 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Life-threatening | 0 | 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Any nonserious adverse event | 3 | 25.0 (5.5, 57.2) | 121.8 | (25.1, 355.8) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Related[g] | 3 | 25.0 (5.5, 57.2) | 121.8 | (25.1, 355.8) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Severe | 0 | 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Life-threatening | 0 | 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Related[g] | 0 | 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Severe | 0 | 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Life-threatening | 0 | 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Death | 0 | 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
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## 14.51. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country – Blinded Follow-Up Period – Safety Population Country: Brazil

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=580, TE[b]=1.6) | | | | Placebo (N[a]=582, TE[b]=1.6) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 414 | 71.4 (67.5, 75.0) | 256.1 | (232.0, 282.0) | 92 | 15.8 (12.9, 19.0) | 57.3 | (46.2, 70.3) |
| Related[g] | 411 | 70.9 (67.0, 74.5) | 254.2 | (230.2, 280.0) | 76 | 13.1 (10.4, 16.1) | 47.4 | (37.3, 59.3) |
| Severe | 4 | 0.7 (0.2, 1.8) | 2.5 | (0.7, 6.3) | 4 | 0.7 (0.2, 1.8) | 2.5 | (0.7, 6.4) |
| Life-threatening | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Any serious adverse event | 5 | 0.9 (0.3, 2.0) | 3.1 | (1.0, 7.2) | 5 | 0.9 (0.3, 2.0) | 3.1 | (1.0, 7.3) |
| Related[g] | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Severe | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 3 | 0.5 (0.1, 1.5) | 1.9 | (0.4, 5.5) |
| Life-threatening | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Any nonserious adverse event | 413 | 71.2 (67.3, 74.9) | 255.4 | (231.4, 281.3) | 90 | 15.5 (12.6, 18.7) | 56.1 | (45.1, 68.9) |
| Related[g] | 411 | 70.9 (67.0, 74.5) | 254.2 | (230.2, 280.0) | 76 | 13.1 (10.4, 16.1) | 47.4 | (37.3, 59.3) |
| Severe | 3 | 0.5 (0.1, 1.5) | 1.9 | (0.4, 5.4) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Life-threatening | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Related[g] | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Severe | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Life-threatening | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Death | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
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## 14.52. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country – Blinded Follow-Up Period – Safety Population Country: South Africa

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=123, TE[b]=0.4) | | | | Placebo (N[a]=128, TE[b]=0.3) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 8 | 6.5 (2.8, 12.4) | 19.7 | (8.5, 38.7) | 2 | 1.6 (0.2, 5.5) | 5.8 | (0.7, 21.0) |
| Related[g] | 7 | 5.7 (2.3, 11.4) | 17.2 | (6.9, 35.4) | 1 | 0.8 (0.0, 4.3) | 2.9 | (0.1, 16.2) |
| Severe | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Life-threatening | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Any serious adverse event | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Related[g] | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Severe | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Life-threatening | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Any nonserious adverse event | 8 | 6.5 (2.8, 12.4) | 19.7 | (8.5, 38.7) | 2 | 1.6 (0.2, 5.5) | 5.8 | (0.7, 21.0) |
| Related[g] | 7 | 5.7 (2.3, 11.4) | 17.2 | (6.9, 35.4) | 1 | 0.8 (0.0, 4.3) | 2.9 | (0.1, 16.2) |
| Severe | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Life-threatening | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Related[g] | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Severe | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Life-threatening | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Death | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (20:50)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: /nda2_ubBIA/C4591031_A_SBLA/adae_s092_cnty_6m_saf

## 14.53. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 913 | 21.0 (19.8, 22.2) | 82.8 | (77.6, 88.4) | 300 | 7.0 (6.2, 7.8) | 32.1 | (28.6, 36.0) |
| Related[g] | 788 | 18.1 (17.0, 19.3) | 71.5 | (66.6, 76.7) | 136 | 3.2 (2.7, 3.7) | 14.6 | (12.2, 17.2) |
| Severe | 51 | 1.2 (0.9, 1.5) | 4.6 | (3.4, 6.1) | 30 | 0.7 (0.5, 1.0) | 3.2 | (2.2, 4.6) |
| Life-threatening | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) |
| Any serious adverse event | 34 | 0.8 (0.5, 1.1) | 3.1 | (2.1, 4.3) | 30 | 0.7 (0.5, 1.0) | 3.2 | (2.2, 4.6) |
| Related[g] | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Severe | 22 | 0.5 (0.3, 0.8) | 2.0 | (1.3, 3.0) | 23 | 0.5 (0.3, 0.8) | 2.5 | (1.6, 3.7) |
| Life-threatening | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) |
| Any nonserious adverse event | 892 | 20.5 (19.3, 21.7) | 80.9 | (75.7, 86.4) | 285 | 6.6 (5.9, 7.4) | 30.5 | (27.1, 34.3) |
| Related[g] | 786 | 18.1 (16.9, 19.2) | 71.3 | (66.4, 76.5) | 136 | 3.2 (2.7, 3.7) | 14.6 | (12.2, 17.2) |
| Severe | 33 | 0.8 (0.5, 1.1) | 3.0 | (2.1, 4.2) | 10 | 0.2 (0.1, 0.4) | 1.1 | (0.5, 2.0) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Severe | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Death | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (20:50)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s092_cnty_6m_saf

## 14.54. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Positive

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=283, TE[b]=0.8) | | | | Placebo (N[a]=259, TE[b]=0.6) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 71 | 25.1 (20.1, 30.6) | 83.8 | (65.5, 105.8) | 25 | 9.7 (6.3, 13.9) | 39.0 | (25.2, 57.6) |
| Related[g] | 67 | 23.7 (18.8, 29.1) | 79.1 | (61.3, 100.5) | 15 | 5.8 (3.3, 9.4) | 23.4 | (13.1, 38.6) |
| Severe | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 2 | 0.8 (0.1, 2.8) | 3.1 | (0.4, 11.3) |
| Life-threatening | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Any serious adverse event | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 3 | 1.2 (0.2, 3.3) | 4.7 | (1.0, 13.7) |
| Related[g] | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Severe | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 2 | 0.8 (0.1, 2.8) | 3.1 | (0.4, 11.3) |
| Life-threatening | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Any nonserious adverse event | 71 | 25.1 (20.1, 30.6) | 83.8 | (65.5, 105.8) | 22 | 8.5 (5.4, 12.6) | 34.3 | (21.5, 52.0) |
| Related[g] | 67 | 23.7 (18.8, 29.1) | 79.1 | (61.3, 100.5) | 15 | 5.8 (3.3, 9.4) | 23.4 | (13.1, 38.6) |
| Severe | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Life-threatening | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Related[g] | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Severe | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Life-threatening | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Death | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |

## 14.54. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Positive

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=283, TE[b]=0.8) | | | | Placebo (N[a]=259, TE[b]=0.6) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (23:13)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File:
./nda2 ubBIA/C4591031 A SBLA/adae s092 base 6m saf

## 14.55. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 1262 | 26.5 (25.2, 27.8) | 103.6 | (97.9, 109.5) | 368 | 7.7 (7.0, 8.5) | 34.6 | (31.2, 38.3) |
| Related[g] | 1138 | 23.9 (22.7, 25.1) | 93.4 | (88.1, 99.0) | 198 | 4.2 (3.6, 4.8) | 18.6 | (16.1, 21.4) |
| Severe | 54 | 1.1 (0.9, 1.5) | 4.4 | (3.3, 5.8) | 32 | 0.7 (0.5, 0.9) | 3.0 | (2.1, 4.2) |
| Life-threatening | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 5 | 0.1 (0.0, 0.2) | 0.5 | (0.2, 1.1) |
| Any serious adverse event | 39 | 0.8 (0.6, 1.1) | 3.2 | (2.3, 4.4) | 32 | 0.7 (0.5, 0.9) | 3.0 | (2.1, 4.2) |
| Related[g] | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Severe | 23 | 0.5 (0.3, 0.7) | 1.9 | (1.2, 2.8) | 24 | 0.5 (0.3, 0.8) | 2.3 | (1.4, 3.4) |
| Life-threatening | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 5 | 0.1 (0.0, 0.2) | 0.5 | (0.2, 1.1) |
| Any nonserious adverse event | 1240 | 26.0 (24.8, 27.3) | 101.8 | (96.2, 107.6) | 354 | 7.4 (6.7, 8.2) | 33.3 | (29.9, 36.9) |
| Related[g] | 1136 | 23.8 (22.6, 25.1) | 93.2 | (87.9, 98.8) | 198 | 4.2 (3.6, 4.8) | 18.6 | (16.1, 21.4) |
| Severe | 35 | 0.7 (0.5, 1.0) | 2.9 | (2.0, 4.0) | 11 | 0.2 (0.1, 0.4) | 1.0 | (0.5, 1.9) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Severe | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Death | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |

## 14.55. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (23:13)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2 ubBIA/C4591031 A SBLA/adae s092 base 6m saf

## 14.56. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date – Blinded Follow-Up Period – HIV-Positive Participants – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=26, TE[b]=0.1) | | | | Placebo (N[a]=24, TE[b]=0.1) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 1 | 3.8 (0.1, 19.6) | 11.5 | (0.3, 64.1) | 1 | 4.2 (0.1, 21.1) | 19.7 | (0.5, 109.5) |
| Related[g] | 1 | 3.8 (0.1, 19.6) | 11.5 | (0.3, 64.1) | 1 | 4.2 (0.1, 21.1) | 19.7 | (0.5, 109.5) |
| Severe | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Life-threatening | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Any serious adverse event | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Related[g] | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Severe | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Life-threatening | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Any nonserious adverse event | 1 | 3.8 (0.1, 19.6) | 11.5 | (0.3, 64.1) | 1 | 4.2 (0.1, 21.1) | 19.7 | (0.5, 109.5) |
| Related[g] | 1 | 3.8 (0.1, 19.6) | 11.5 | (0.3, 64.1) | 1 | 4.2 (0.1, 21.1) | 19.7 | (0.5, 109.5) |
| Severe | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Life-threatening | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Related[g] | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Severe | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Life-threatening | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Death | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |

Abbreviation: HIV = human immunodeficiency virus.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 01APR2022 (00:12)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s091_all_hiv_saf

## 14.57. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 1335 | 26.4 (25.2, 27.6) | 102.3 | (96.9, 108.0) | 394 | 7.8 (7.1, 8.6) | 34.9 | (31.5, 38.5) |
| Blood and lymphatic system disorders | 142 | 2.8 (2.4, 3.3) | 10.9 | (9.2, 12.8) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Anaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Iron deficiency anaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lymph node pain | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lymphadenitis | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lymphadenopathy | 135 | 2.7 (2.2, 3.2) | 10.3 | (8.7, 12.2) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Lymphocytosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lymphopenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Neutropenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Thrombocytopenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cardiac disorders | 13 | 0.3 (0.1, 0.4) | 1.0 | (0.5, 1.7) | 7 | 0.1 (0.1, 0.3) | 0.6 | (0.2, 1.3) |
| Acute myocardial infarction | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Atrial fibrillation | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Atrial flutter | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cardiac failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Coronary artery insufficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Palpitations | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pericarditis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Supraventricular tachycardia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Tachycardia | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Congenital, familial and genetic disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Thalassaemia beta | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ear and labyrinth disorders | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Ear pain | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Tinnitus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Vertigo | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vertigo positional | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Endocrine disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |

## 14.57. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Goitre | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hypothyroidism | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Thyroid cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Thyroid mass | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Eye disorders | 11 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.5) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Cataract | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Chalazion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Diplopia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dry age-related macular degeneration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dry eye | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Eye pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Eyelid ptosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Glaucoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Keratitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Macular degeneration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ocular hyperaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Photophobia | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vitreous detachment | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Gastrointestinal disorders | 92 | 1.8 (1.5, 2.2) | 7.1 | (5.7, 8.6) | 47 | 0.9 (0.7, 1.2) | 4.2 | (3.1, 5.5) |
| Abdominal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abdominal pain | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Abdominal pain upper | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Aphthous ulcer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ascites | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Constipation | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dental caries | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dental cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Diarrhoea | 26 | 0.5 (0.3, 0.8) | 2.0 | (1.3, 2.9) | 13 | 0.3 (0.1, 0.4) | 1.2 | (0.6, 2.0) |
| Diverticulum | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dry mouth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dyspepsia | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Gastric fistula | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Gastrooesophageal reflux disease | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Gingival pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Haemorrhoids | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hypoaesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hypoaesthesia teeth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.57. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Inguinal hernia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nausea | 51 | 1.0 (0.8, 1.3) | 3.9 | (2.9, 5.1) | 17 | 0.3 (0.2, 0.5) | 1.5 | (0.9, 2.4) |
| Oesophageal ulcer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Paraesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Parotid duct obstruction | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Toothache | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Vomiting | 12 | 0.2 (0.1, 0.4) | 0.9 | (0.5, 1.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| General disorders and administration site conditions | 1083 | 21.4 (20.3, 22.6) | 83.0 | (78.2, 88.1) | 163 | 3.2 (2.8, 3.8) | 14.4 | (12.3, 16.8) |
| Asthenia | 8 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.2) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Axillary pain | 13 | 0.3 (0.1, 0.4) | 1.0 | (0.5, 1.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Chest discomfort | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Chest pain | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Chills | 237 | 4.7 (4.1, 5.3) | 18.2 | (15.9, 20.6) | 11 | 0.2 (0.1, 0.4) | 1.0 | (0.5, 1.7) |
| Cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Drug withdrawal syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Fatigue | 378 | 7.4 (6.7, 8.1) | 28.6 | (25.8, 31.6) | 64 | 1.3 (1.0, 1.6) | 5.7 | (4.4, 7.2) |
| Feeling abnormal | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Feeling hot | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Granuloma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injection site bruising | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Injection site discomfort | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site erythema | 22 | 0.4 (0.3, 0.7) | 1.7 | (1.1, 2.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site hypoaesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site induration | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site inflammation | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site irritation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site lymphadenopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injection site oedema | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site pain | 657 | 13.0 (12.1, 14.0) | 50.4 | (46.6, 54.4) | 80 | 1.6 (1.3, 2.0) | 7.1 | (5.6, 8.8) |
| Injection site paraesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.57. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Injection site pruritus | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site reaction | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site swelling | 21 | 0.4 (0.3, 0.6) | 1.6 | (1.0, 2.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injection site vesicles | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site warmth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injury associated with device | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Malaise | 35 | 0.7 (0.5, 1.0) | 2.7 | (1.9, 3.7) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Metaplasia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pain | 137 | 2.7 (2.3, 3.2) | 10.5 | (8.8, 12.4) | 17 | 0.3 (0.2, 0.5) | 1.5 | (0.9, 2.4) |
| Peripheral swelling | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Pyrexia | 251 | 5.0 (4.4, 5.6) | 19.2 | (16.9, 21.8) | 8 | 0.2 (0.1, 0.3) | 0.7 | (0.3, 1.4) |
| Sluggishness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Swelling | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vaccination site pain | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vaccination site rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hepatobiliary disorders | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Bile duct stone | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cholelithiasis | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hepatic cirrhosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hepatic steatosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Immune system disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Allergic oedema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Allergy to arthropod sting | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Food allergy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Seasonal allergy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Infections and infestations | 36 | 0.7 (0.5, 1.0) | 2.8 | (1.9, 3.8) | 43 | 0.9 (0.6, 1.2) | 3.8 | (2.8, 5.1) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Abscess | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Acute sinusitis | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Adenoiditis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Appendicitis | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Appendicitis perforated | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.57. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Arthritis infective | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Candida infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Cellulitis | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Conjunctivitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Conjunctivitis bacterial | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cystitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Device related infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Diverticulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Ear infection | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Empyema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Epididymitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Eye infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Groin abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hand-foot-and-mouth disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Helicobacter infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Herpes zoster | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Hordeolum | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Infected dermal cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Kidney infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Latent tuberculosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Mastitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Onychomycosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Oral herpes | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Otitis externa | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Otitis media | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Otitis media acute | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Peritonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Rhinitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Salmonellosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Sepsis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Septic shock | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Sinusitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Tooth abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

## 14.57. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Tooth infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Urinary tract infection | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 9 | 0.2 (0.1, 0.3) | 0.8 | (0.4, 1.5) |
| Varicella zoster virus infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vestibular neuronitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vulvovaginal mycotic infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injury, poisoning and procedural complications | 24 | 0.5 (0.3, 0.7) | 1.8 | (1.2, 2.7) | 36 | 0.7 (0.5, 1.0) | 3.2 | (2.2, 4.4) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Animal bite | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Ankle fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Arthropod sting | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Bone contusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Burns third degree | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cartilage injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Concussion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Contusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Corneal abrasion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Craniocerebral injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Exposure during pregnancy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Fall | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 10 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.6) |
| Head injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hip fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Humerus fracture | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Joint injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Ligament rupture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ligament sprain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Limb crushing injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Limb injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Meniscus injury | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Muscle strain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Musculoskeletal injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Neck injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Periorbital haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Post procedural haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Procedural pain | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.57. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Road traffic accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Skin abrasion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Skin laceration | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Stoma complication | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Stress fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Tendon rupture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Tibia fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Tooth fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Wrist fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Investigations | 35 | 0.7 (0.5, 1.0) | 2.7 | (1.9, 3.7) | 13 | 0.3 (0.1, 0.4) | 1.2 | (0.6, 2.0) |
| Alpha 1 foetoprotein increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Antinuclear antibody positive | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Blood cholesterol increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Blood creatinine increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Blood glucose increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Blood pressure increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Body temperature increased | 30 | 0.6 (0.4, 0.8) | 2.3 | (1.6, 3.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Heart rate increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hepatic enzyme increased | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Inflammatory marker increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lipase increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Prostatic specific antigen increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Respiratory rate increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Metabolism and nutrition disorders | 20 | 0.4 (0.2, 0.6) | 1.5 | (0.9, 2.4) | 12 | 0.2 (0.1, 0.4) | 1.1 | (0.5, 1.9) |
| Decreased appetite | 9 | 0.2 (0.1, 0.3) | 0.7 | (0.3, 1.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dehydration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Diabetes mellitus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Diabetic ketoacidosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Glucose tolerance impaired | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.57. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Gout | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Hypercholesterolaemia | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hypokalaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hyponatraemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Iron deficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Type 2 diabetes mellitus | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Vitamin D deficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Musculoskeletal and connective tissue disorders | 355 | 7.0 (6.3, 7.8) | 27.2 | (24.5, 30.2) | 55 | 1.1 (0.8, 1.4) | 4.9 | (3.7, 6.3) |
| Arthralgia | 42 | 0.8 (0.6, 1.1) | 3.2 | (2.3, 4.4) | 16 | 0.3 (0.2, 0.5) | 1.4 | (0.8, 2.3) |
| Arthritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Back pain | 8 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.2) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Bone cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Bone pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Foot deformity | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Groin pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Joint effusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Joint stiffness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Joint swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Metatarsalgia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Muscle fatigue | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Muscle swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Muscular weakness | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Musculoskeletal chest pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Musculoskeletal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Musculoskeletal pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Musculoskeletal stiffness | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Myalgia | 241 | 4.8 (4.2, 5.4) | 18.5 | (16.2, 21.0) | 20 | 0.4 (0.2, 0.6) | 1.8 | (1.1, 2.7) |
| Neck pain | 10 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.4) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Osteoarthritis | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Osteoporosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pain in extremity | 57 | 1.1 (0.9, 1.5) | 4.4 | (3.3, 5.7) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Pain in jaw | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Plantar fasciitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

## 14.57. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Psoriatic arthropathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Rotator cuff syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Scoliosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Spinal stenosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Synovial cyst | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Tendonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Trigger finger | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 15 | 0.3 (0.2, 0.5) | 1.1 | (0.6, 1.9) | 11 | 0.2 (0.1, 0.4) | 1.0 | (0.5, 1.7) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Basal cell carcinoma | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Benign neoplasm of thyroid gland | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Breast cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Focal nodular hyperplasia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Granular cell tumour | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Malignant melanoma | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Melanocytic naevus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Prostate cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Skin cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Squamous cell carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Squamous cell carcinoma of skin | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Uterine leiomyoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nervous system disorders | 297 | 5.9 (5.2, 6.6) | 22.8 | (20.3, 25.5) | 69 | 1.4 (1.1, 1.7) | 6.1 | (4.8, 7.7) |

## 14.57. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Altered state of consciousness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Bell's palsy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Carpal tunnel syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cervical radiculopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cervicobrachial syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dizziness | 9 | 0.2 (0.1, 0.3) | 0.7 | (0.3, 1.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Dysgeusia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Headache | 260 | 5.1 (4.6, 5.8) | 19.9 | (17.6, 22.5) | 51 | 1.0 (0.8, 1.3) | 4.5 | (3.4, 5.9) |
| Hyperaesthesia | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hypoaesthesia | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hypotonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Lethargy | 12 | 0.2 (0.1, 0.4) | 0.9 | (0.5, 1.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Migraine | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Migraine with aura | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nerve compression | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Neuralgic amyotrophy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Paraesthesia | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Parosmia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Sciatica | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Seizure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Somnolence | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Syncope | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Taste disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Tension headache | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Tremor | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pregnancy, puerperium and perinatal conditions | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abortion spontaneous | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pregnancy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Psychiatric disorders | 17 | 0.3 (0.2, 0.5) | 1.3 | (0.8, 2.1) | 15 | 0.3 (0.2, 0.5) | 1.3 | (0.7, 2.2) |
| Abnormal dreams | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.57. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Adjustment disorder with mixed anxiety and depressed mood | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Alcoholism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Anxiety | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Attention deficit hyperactivity disorder | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Depression | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Generalised anxiety disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Insomnia | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Mood altered | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nightmare | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Poor quality sleep | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Stress | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Renal and urinary disorders | 11 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.5) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Cystitis haemorrhagic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dysuria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Haematuria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nephrolithiasis | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Renal colic | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Renal cyst | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Stress urinary incontinence | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Urinary incontinence | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Reproductive system and breast disorders | 10 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.4) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Atrophic vulvovaginitis | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Breast calcifications | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Breast pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Endometriosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Heavy menstrual bleeding | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Intermenstrual bleeding | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Menstruation irregular | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ovarian cyst | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Prostatitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Scrotal disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.57. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Respiratory, thoracic and mediastinal disorders | 15 | 0.3 (0.2, 0.5) | 1.1 | (0.6, 1.9) | 17 | 0.3 (0.2, 0.5) | 1.5 | (0.9, 2.4) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Asthma | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Asthma exercise induced | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dry throat | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Epistaxis | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nasal congestion | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Nasal polyps | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pharyngeal swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pleural effusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pleurisy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pulmonary congestion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Respiratory failure | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Rhinorrhoea | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Sinus congestion | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Sleep apnoea syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Sneezing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Throat tightness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Skin and subcutaneous tissue disorders | 25 | 0.5 (0.3, 0.7) | 1.9 | (1.2, 2.8) | 12 | 0.2 (0.1, 0.4) | 1.1 | (0.5, 1.9) |
| Alopecia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Alopecia areata | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cold sweat | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dermal cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Dermatitis allergic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dermatitis contact | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dry skin | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Erythema | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hyperhidrosis | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intertrigo | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Night sweats | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pruritus | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Psoriasis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Rash | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

## 14.57. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Rash erythematous | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Rash papular | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Urticaria | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Xanthoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Surgical and medical procedures | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abortion induced | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Bunion operation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Gastrectomy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vascular disorders | 7 | 0.1 (0.1, 0.3) | 0.5 | (0.2, 1.1) | 12 | 0.2 (0.1, 0.4) | 1.1 | (0.5, 1.9) |
| Deep vein thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Flushing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Haematoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hot flush | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Hypertension | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Hypotension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Peripheral venous disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 01APR2022 (02:51)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ub3IA/C4591031_A_SBLA/adae_s131_all_6m_saf

## 14.58. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 803 | 28.6 (27.0, 30.4) | 110.1 | (102.6, 118.0) | 219 | 7.9 (6.9, 8.9) | 34.2 | (29.8, 39.1) |
| Blood and lymphatic system disorders | 118 | 4.2 (3.5, 5.0) | 16.2 | (13.4, 19.4) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Iron deficiency anaemia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Lymph node pain | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Lymphadenitis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Lymphadenopathy | 112 | 4.0 (3.3, 4.8) | 15.4 | (12.6, 18.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Lymphocytosis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Lymphopenia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Neutropenia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Thrombocytopenia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Cardiac disorders | 6 | 0.2 (0.1, 0.5) | 0.8 | (0.3, 1.8) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Palpitations | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Supraventricular tachycardia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Tachycardia | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Congenital, familial and genetic disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Thalassaemia beta | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Ear and labyrinth disorders | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Ear pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Tinnitus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Vertigo | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Vertigo positional | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Endocrine disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Goitre | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Hypothyroidism | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Thyroid cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Eye disorders | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Diplopia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Eye pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Ocular hyperaemia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Photophobia | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Gastrointestinal disorders | 53 | 1.9 (1.4, 2.5) | 7.3 | (5.4, 9.5) | 22 | 0.8 (0.5, 1.2) | 3.4 | (2.2, 5.2) |

## 14.58. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Abdominal pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Abdominal pain upper | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Constipation | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Dental caries | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Diarrhoea | 18 | 0.6 (0.4, 1.0) | 2.5 | (1.5, 3.9) | 7 | 0.3 (0.1, 0.5) | 1.1 | (0.4, 2.3) |
| Dry mouth | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Dyspepsia | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Gastric fistula | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Gastrooesophageal reflux disease | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Hypoaesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Hypoaesthesia teeth | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Nausea | 24 | 0.9 (0.5, 1.3) | 3.3 | (2.1, 4.9) | 9 | 0.3 (0.1, 0.6) | 1.4 | (0.6, 2.7) |
| Paraesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Parotid duct obstruction | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Small intestinal obstruction | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Toothache | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Vomiting | 7 | 0.2 (0.1, 0.5) | 1.0 | (0.4, 2.0) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| General disorders and administration site conditions | 671 | 23.9 (22.4, 25.6) | 92.0 | (85.2, 99.2) | 97 | 3.5 (2.8, 4.2) | 15.2 | (12.3, 18.5) |
| Asthenia | 5 | 0.2 (0.1, 0.4) | 0.7 | (0.2, 1.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Axillary pain | 10 | 0.4 (0.2, 0.7) | 1.4 | (0.7, 2.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Chest discomfort | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Chest pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Chills | 152 | 5.4 (4.6, 6.3) | 20.8 | (17.7, 24.4) | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) |
| Drug withdrawal syndrome | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Fatigue | 212 | 7.6 (6.6, 8.6) | 29.1 | (25.3, 33.3) | 37 | 1.3 (0.9, 1.8) | 5.8 | (4.1, 8.0) |
| Feeling abnormal | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Feeling hot | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Granuloma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Injection site bruising | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Injection site discomfort | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site erythema | 10 | 0.4 (0.2, 0.7) | 1.4 | (0.7, 2.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site induration | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site inflammation | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site oedema | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |

## 14.58. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Injection site pain | 417 | 14.9 (13.6, 16.2) | 57.2 | (51.8, 62.9) | 50 | 1.8 (1.3, 2.4) | 7.8 | (5.8, 10.3) |
| Injection site paraesthesia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site pruritus | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site reaction | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site swelling | 11 | 0.4 (0.2, 0.7) | 1.5 | (0.8, 2.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injury associated with device | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Malaise | 25 | 0.9 (0.6, 1.3) | 3.4 | (2.2, 5.1) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Metaplasia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pain | 82 | 2.9 (2.3, 3.6) | 11.2 | (8.9, 14.0) | 8 | 0.3 (0.1, 0.6) | 1.3 | (0.5, 2.5) |
| Peripheral swelling | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Pyrexia | 158 | 5.6 (4.8, 6.6) | 21.7 | (18.4, 25.3) | 4 | 0.1 (0.0, 0.4) | 0.6 | (0.2, 1.6) |
| Sluggishness | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Swelling | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Vaccination site pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Vaccination site rash | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Hepatobiliary disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Bile duct stone | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Cholelithiasis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Hepatic steatosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Immune system disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Allergic oedema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Seasonal allergy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Infections and infestations | 18 | 0.6 (0.4, 1.0) | 2.5 | (1.5, 3.9) | 22 | 0.8 (0.5, 1.2) | 3.4 | (2.2, 5.2) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Acute sinusitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Adenoiditis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Appendicitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Arthritis infective | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Candida infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Conjunctivitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Conjunctivitis bacterial | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Ear infection | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |

## 14.58. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Epididymitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Eye infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Groin abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Hand-foot-and-mouth disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Helicobacter infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Herpes zoster | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Hordeolum | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Kidney infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Latent tuberculosis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Mastitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Oral herpes | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Otitis externa | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Otitis media | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Septic shock | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Sinusitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Tooth abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Tooth infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Urinary tract infection | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 4 | 0.1 (0.0, 0.4) | 0.6 | (0.2, 1.6) |
| Injury, poisoning and procedural complications | 13 | 0.5 (0.2, 0.8) | 1.8 | (0.9, 3.0) | 21 | 0.8 (0.5, 1.2) | 3.3 | (2.0, 5.0) |
| Animal bite | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Ankle fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Arthropod sting | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Bone contusion | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Cartilage injury | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Concussion | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Contusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Corneal abrasion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Exposure during pregnancy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Fall | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 5 | 0.2 (0.1, 0.4) | 0.8 | (0.3, 1.8) |
| Head injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Humerus fracture | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Joint injury | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Ligament rupture | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |

## 14.58. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Ligament sprain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Meniscus injury | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Muscle strain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Musculoskeletal injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Post procedural haemorrhage | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Procedural pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Road traffic accident | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Skin abrasion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Skin laceration | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Stoma complication | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Tibia fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Tooth fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Wrist fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Investigations | 22 | 0.8 (0.5, 1.2) | 3.0 | (1.9, 4.6) | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) |
| Blood cholesterol increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Blood pressure increased | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Body temperature increased | 19 | 0.7 (0.4, 1.1) | 2.6 | (1.6, 4.1) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Heart rate increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Hepatic enzyme increased | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Inflammatory marker increased | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Respiratory rate increased | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Metabolism and nutrition disorders | 7 | 0.2 (0.1, 0.5) | 1.0 | (0.4, 2.0) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Decreased appetite | 5 | 0.2 (0.1, 0.4) | 0.7 | (0.2, 1.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Diabetic ketoacidosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Iron deficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Type 2 diabetes mellitus | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Musculoskeletal and connective tissue disorders | 212 | 7.6 (6.6, 8.6) | 29.1 | (25.3, 33.3) | 29 | 1.0 (0.7, 1.5) | 4.5 | (3.0, 6.5) |
| Arthralgia | 22 | 0.8 (0.5, 1.2) | 3.0 | (1.9, 4.6) | 7 | 0.3 (0.1, 0.5) | 1.1 | (0.4, 2.3) |
| Back pain | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Bone pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |

## 14.58. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Muscle fatigue | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Muscular weakness | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Musculoskeletal chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Musculoskeletal pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Musculoskeletal stiffness | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Myalgia | 157 | 5.6 (4.8, 6.5) | 21.5 | (18.3, 25.2) | 14 | 0.5 (0.3, 0.8) | 2.2 | (1.2, 3.7) |
| Neck pain | 5 | 0.2 (0.1, 0.4) | 0.7 | (0.2, 1.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Pain in extremity | 27 | 1.0 (0.6, 1.4) | 3.7 | (2.4, 5.4) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pain in jaw | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Rotator cuff syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Scoliosis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Spinal stenosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Synovial cyst | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Tendonitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Focal nodular hyperplasia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Granular cell tumour | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Squamous cell carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Uterine leiomyoma | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Nervous system disorders | 182 | 6.5 (5.6, 7.5) | 25.0 | (21.5, 28.9) | 41 | 1.5 (1.1, 2.0) | 6.4 | (4.6, 8.7) |
| Bell's palsy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Carpal tunnel syndrome | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Cervical radiculopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Dizziness | 7 | 0.2 (0.1, 0.5) | 1.0 | (0.4, 2.0) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Headache | 160 | 5.7 (4.9, 6.6) | 21.9 | (18.7, 25.6) | 30 | 1.1 (0.7, 1.5) | 4.7 | (3.2, 6.7) |
| Hyperaesthesia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Hypoaesthesia | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Hypotonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |

## 14.58. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Lethargy | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Migraine | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Nerve compression | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Neuralgic amyotrophy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Paraesthesia | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Parosmia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Sciatica | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Seizure | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Somnolence | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Taste disorder | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Tension headache | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Tremor | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Pregnancy, puerperium and perinatal conditions | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Abortion spontaneous | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pregnancy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Psychiatric disorders | 12 | 0.4 (0.2, 0.7) | 1.6 | (0.9, 2.9) | 12 | 0.4 (0.2, 0.8) | 1.9 | (1.0, 3.3) |
| Abnormal dreams | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Adjustment disorder with mixed anxiety and depressed mood | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Anxiety | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Attention deficit hyperactivity disorder | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 4 | 0.1 (0.0, 0.4) | 0.6 | (0.2, 1.6) |
| Depression | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Generalised anxiety disorder | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Insomnia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Mood altered | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Nightmare | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Stress | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Renal and urinary disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Reproductive system and breast disorders | 5 | 0.2 (0.1, 0.4) | 0.7 | (0.2, 1.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |

## 14.58. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Endometriosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Heavy menstrual bleeding | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Intermenstrual bleeding | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Menstruation irregular | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Ovarian cyst | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Respiratory, thoracic and mediastinal disorders | 6 | 0.2 (0.1, 0.5) | 0.8 | (0.3, 1.8) | 9 | 0.3 (0.1, 0.6) | 1.4 | (0.6, 2.7) |
| Asthma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Asthma exercise induced | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Dry throat | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Nasal congestion | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Nasal polyps | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pharyngeal swelling | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Pleurisy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pulmonary congestion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Rhinorrhoea | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Sneezing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Throat tightness | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Skin and subcutaneous tissue disorders | 13 | 0.5 (0.2, 0.8) | 1.8 | (0.9, 3.0) | 7 | 0.3 (0.1, 0.5) | 1.1 | (0.4, 2.3) |
| Alopecia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Cold sweat | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Dermal cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Dermatitis allergic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Erythema | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Hyperhidrosis | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Night sweats | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Pruritus | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Rash | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Rash erythematous | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Rash papular | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Urticaria | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Surgical and medical procedures | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |

## 14.58. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Abortion induced | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Vascular disorders | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) |
| Flushing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Hot flush | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Hypertension | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Hypotension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:18)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_age_6m_saf

## 14.59. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 532 | 23.6 (21.9, 25.4) | 92.5 | (84.8, 100.7) | 175 | 7.8 (6.7, 9.0) | 35.8 | (30.7, 41.5) |
| Blood and lymphatic system disorders | 24 | 1.1 (0.7, 1.6) | 4.2 | (2.7, 6.2) | 3 | 0.1 (0.0, 0.4) | 0.6 | (0.1, 1.8) |
| Anaemia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Lymphadenopathy | 23 | 1.0 (0.6, 1.5) | 4.0 | (2.5, 6.0) | 3 | 0.1 (0.0, 0.4) | 0.6 | (0.1, 1.8) |
| Cardiac disorders | 7 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.5) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Acute myocardial infarction | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Atrial fibrillation | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Atrial flutter | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Cardiac failure | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Coronary artery insufficiency | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Palpitations | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Pericarditis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Tachycardia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Ear and labyrinth disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Ear pain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Endocrine disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 3 | 0.1 (0.0, 0.4) | 0.6 | (0.1, 1.8) |
| Goitre | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Hypothyroidism | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Thyroid mass | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Eye disorders | 7 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.5) | 3 | 0.1 (0.0, 0.4) | 0.6 | (0.1, 1.8) |
| Cataract | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Chalazion | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Dry age-related macular degeneration | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Dry eye | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Eyelid ptosis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Glaucoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Keratitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Macular degeneration | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Vitreous detachment | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Gastrointestinal disorders | 39 | 1.7 (1.2, 2.4) | 6.8 | (4.8, 9.3) | 25 | 1.1 (0.7, 1.6) | 5.1 | (3.3, 7.5) |
| Abdominal discomfort | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |

## 14.59. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Abdominal pain upper | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Aphthous ulcer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Ascites | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Dental cyst | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Diarrhoea | 8 | 0.4 (0.2, 0.7) | 1.4 | (0.6, 2.7) | 6 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.7) |
| Diverticulum | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Dyspepsia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Gastrooesophageal reflux disease | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Gingival pain | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Haemorrhoids | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Inguinal hernia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Nausea | 27 | 1.2 (0.8, 1.7) | 4.7 | (3.1, 6.8) | 8 | 0.4 (0.2, 0.7) | 1.6 | (0.7, 3.2) |
| Oesophageal ulcer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Toothache | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Vomiting | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| General disorders and administration site conditions | 412 | 18.3 (16.7, 20.0) | 71.6 | (64.9, 78.9) | 66 | 2.9 (2.3, 3.7) | 13.5 | (10.4, 17.2) |
| Asthenia | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Axillary pain | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Chest discomfort | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Chills | 85 | 3.8 (3.0, 4.6) | 14.8 | (11.8, 18.3) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Cyst | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Fatigue | 161 | 7.2 (6.1, 8.3) | 28.0 | (23.8, 32.7) | 27 | 1.2 (0.8, 1.7) | 5.5 | (3.6, 8.0) |
| Injection site bruising | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site erythema | 12 | 0.5 (0.3, 0.9) | 2.1 | (1.1, 3.6) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site hypoaesthesia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site inflammation | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site irritation | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site lymphadenopathy | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Injection site oedema | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site pain | 240 | 10.7 (9.4, 12.0) | 41.7 | (36.6, 47.4) | 30 | 1.3 (0.9, 1.9) | 6.1 | (4.1, 8.8) |

## 14.59. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Injection site pruritus | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site rash | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site reaction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site swelling | 10 | 0.4 (0.2, 0.8) | 1.7 | (0.8, 3.2) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Injection site vesicles | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site warmth | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Malaise | 10 | 0.4 (0.2, 0.8) | 1.7 | (0.8, 3.2) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Pain | 55 | 2.4 (1.8, 3.2) | 9.6 | (7.2, 12.4) | 9 | 0.4 (0.2, 0.8) | 1.8 | (0.8, 3.5) |
| Peripheral swelling | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Pyrexia | 93 | 4.1 (3.3, 5.0) | 16.2 | (13.1, 19.8) | 4 | 0.2 (0.0, 0.5) | 0.8 | (0.2, 2.1) |
| Swelling | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Hepatobiliary disorders | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Cholelithiasis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Hepatic cirrhosis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Immune system disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Allergy to arthropod sting | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Food allergy | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Infections and infestations | 18 | 0.8 (0.5, 1.3) | 3.1 | (1.9, 4.9) | 21 | 0.9 (0.6, 1.4) | 4.3 | (2.7, 6.6) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Abscess | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Acute sinusitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Appendicitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Appendicitis perforated | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Candida infection | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Cellulitis | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Cystitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Device related infection | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Diverticulitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Ear infection | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Empyema | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Eye infection | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Herpes zoster | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Infected dermal cyst | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Kidney infection | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Onychomycosis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Otitis externa | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |

## 14.59. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Otitis media acute | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Peritonitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Rhinitis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Salmonellosis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Sepsis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Sinusitis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Tooth infection | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Urinary tract infection | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Varicella zoster virus infection | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Vestibular neuronitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Vulvovaginal mycotic infection | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Injury, poisoning and procedural complications | 11 | 0.5 (0.2, 0.9) | 1.9 | (1.0, 3.4) | 15 | 0.7 (0.4, 1.1) | 3.1 | (1.7, 5.1) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Arthropod sting | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Burns third degree | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Craniocerebral injury | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Fall | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Hip fracture | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Humerus fracture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Ligament sprain | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Limb crushing injury | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Limb injury | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Meniscus injury | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Muscle strain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Neck injury | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Periorbital haemorrhage | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Skin laceration | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Stress fracture | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Tendon rupture | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Investigations | 13 | 0.6 (0.3, 1.0) | 2.3 | (1.2, 3.9) | 7 | 0.3 (0.1, 0.6) | 1.4 | (0.6, 2.9) |
| Alpha 1 foetoprotein increased | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |

## 14.59. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Antinuclear antibody positive | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Blood creatinine increased | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Blood glucose increased | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Body temperature increased | 11 | 0.5 (0.2, 0.9) | 1.9 | (1.0, 3.4) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Hepatic enzyme increased | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Lipase increased | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Prostatic specific antigen increased | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Metabolism and nutrition disorders | 13 | 0.6 (0.3, 1.0) | 2.3 | (1.2, 3.9) | 10 | 0.4 (0.2, 0.8) | 2.0 | (1.0, 3.8) |
| Decreased appetite | 4 | 0.2 (0.0, 0.5) | 0.7 | (0.2, 1.8) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Dehydration | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Diabetes mellitus | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Glucose tolerance impaired | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Gout | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 4 | 0.2 (0.0, 0.5) | 0.8 | (0.2, 2.1) |
| Hypercholesterolaemia | 4 | 0.2 (0.0, 0.5) | 0.7 | (0.2, 1.8) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Hypokalaemia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Hyponatraemia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Type 2 diabetes mellitus | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Vitamin D deficiency | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Musculoskeletal and connective tissue disorders | 143 | 6.4 (5.4, 7.4) | 24.9 | (21.0, 29.3) | 26 | 1.2 (0.8, 1.7) | 5.3 | (3.5, 7.8) |
| Arthralgia | 20 | 0.9 (0.5, 1.4) | 3.5 | (2.1, 5.4) | 9 | 0.4 (0.2, 0.8) | 1.8 | (0.8, 3.5) |
| Arthritis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Back pain | 4 | 0.2 (0.0, 0.5) | 0.7 | (0.2, 1.8) | 3 | 0.1 (0.0, 0.4) | 0.6 | (0.1, 1.8) |
| Bone cyst | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Foot deformity | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Groin pain | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Joint effusion | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |

## 14.59. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Joint stiffness | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Joint swelling | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Metatarsalgia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Muscle swelling | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Musculoskeletal chest pain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Musculoskeletal discomfort | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Musculoskeletal pain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Myalgia | 84 | 3.7 (3.0, 4.6) | 14.6 | (11.7, 18.1) | 6 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.7) |
| Neck pain | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Osteoporosis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Pain in extremity | 30 | 1.3 (0.9, 1.9) | 5.2 | (3.5, 7.4) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Plantar fasciitis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Psoriatic arthropathy | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Rotator cuff syndrome | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Tendonitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Trigger finger | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 11 | 0.5 (0.2, 0.9) | 1.9 | (1.0, 3.4) | 10 | 0.4 (0.2, 0.8) | 2.0 | (1.0, 3.8) |
| Basal cell carcinoma | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Benign neoplasm of thyroid gland | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Breast cancer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Malignant melanoma | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Melanocytic naevus | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Prostate cancer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |

## 14.59. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Skin cancer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Squamous cell carcinoma of skin | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Nervous system disorders | 115 | 5.1 (4.2, 6.1) | 20.0 | (16.5, 24.0) | 28 | 1.3 (0.8, 1.8) | 5.7 | (3.8, 8.3) |
| Altered state of consciousness | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Cervicobrachial syndrome | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Dizziness | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Dysgeusia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Headache | 100 | 4.4 (3.6, 5.4) | 17.4 | (14.1, 21.1) | 21 | 0.9 (0.6, 1.4) | 4.3 | (2.7, 6.6) |
| Hyperaesthesia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Hypoaesthesia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Lethargy | 8 | 0.4 (0.2, 0.7) | 1.4 | (0.6, 2.7) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Migraine | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Migraine with aura | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Paraesthesia | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Syncope | 4 | 0.2 (0.0, 0.5) | 0.7 | (0.2, 1.8) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Psychiatric disorders | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) | 3 | 0.1 (0.0, 0.4) | 0.6 | (0.1, 1.8) |
| Alcoholism | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Anxiety | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Depression | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Insomnia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Poor quality sleep | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Renal and urinary disorders | 10 | 0.4 (0.2, 0.8) | 1.7 | (0.8, 3.2) | 3 | 0.1 (0.0, 0.4) | 0.6 | (0.1, 1.8) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Cystitis haemorrhagic | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Dysuria | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Haematuria | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Nephrolithiasis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Renal colic | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Renal cyst | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Stress urinary incontinence | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |

## 14.59. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Urinary incontinence | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Reproductive system and breast disorders | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) | 3 | 0.1 (0.0, 0.4) | 0.6 | (0.1, 1.8) |
| Atrophic vulvovaginitis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Breast calcifications | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Breast pain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Prostatitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Scrotal disorder | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Respiratory, thoracic and mediastinal disorders | 9 | 0.4 (0.2, 0.8) | 1.6 | (0.7, 3.0) | 8 | 0.4 (0.2, 0.7) | 1.6 | (0.7, 3.2) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Asthma | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Epistaxis | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Nasal congestion | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Pleural effusion | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Respiratory failure | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Rhinorrhoea | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Sinus congestion | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Sleep apnoea syndrome | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Sneezing | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Skin and subcutaneous tissue disorders | 12 | 0.5 (0.3, 0.9) | 2.1 | (1.1, 3.6) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Alopecia areata | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Dermal cyst | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Dermatitis contact | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Dry skin | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Hyperhidrosis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Intertrigo | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Night sweats | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Pruritus | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Psoriasis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Rash | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Urticaria | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Xanthoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |

## 14.59. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Surgical and medical procedures | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Bunion operation | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Gastrectomy | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Vascular disorders | 4 | 0.2 (0.0, 0.5) | 0.7 | (0.2, 1.8) | 6 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.7) |
| Deep vein thrombosis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Flushing | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Haematoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Hot flush | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Hypertension | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Peripheral venous disease | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:18)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_age_6m_saf

## 14.60. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Male

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2443, TE[b]=6.2) | | | | Placebo (N[a]=2500, TE[b]=5.7) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 568 | 23.3 (21.6, 25.0) | 91.1 | (83.7, 98.9) | 158 | 6.3 (5.4, 7.3) | 27.9 | (23.7, 32.6) |
| Blood and lymphatic system disorders | 48 | 2.0 (1.5, 2.6) | 7.7 | (5.7, 10.2) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Lymph node pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Lymphadenitis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Lymphadenopathy | 44 | 1.8 (1.3, 2.4) | 7.1 | (5.1, 9.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Cardiac disorders | 9 | 0.4 (0.2, 0.7) | 1.4 | (0.7, 2.7) | 4 | 0.2 (0.0, 0.4) | 0.7 | (0.2, 1.8) |
| Acute myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Atrial fibrillation | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Atrial flutter | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Coronary artery insufficiency | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Palpitations | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Supraventricular tachycardia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Tachycardia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Ear and labyrinth disorders | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Tinnitus | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Vertigo positional | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Endocrine disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Goitre | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hypothyroidism | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Eye disorders | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Glaucoma | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Gastrointestinal disorders | 35 | 1.4 (1.0, 2.0) | 5.6 | (3.9, 7.8) | 16 | 0.6 (0.4, 1.0) | 2.8 | (1.6, 4.6) |
| Abdominal pain upper | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Aphthous ulcer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Ascites | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Constipation | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Dental caries | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Dental cyst | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Diarrhoea | 14 | 0.6 (0.3, 1.0) | 2.2 | (1.2, 3.8) | 4 | 0.2 (0.0, 0.4) | 0.7 | (0.2, 1.8) |
| Dry mouth | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Dyspepsia | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |

## 14.60. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Male

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2443, TE[b]=6.2) | | | | Placebo (N[a]=2500, TE[b]=5.7) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Gastric fistula | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Gastrooesophageal reflux disease | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Gingival pain | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Haemorrhoids | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hypoaesthesia oral | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Inguinal hernia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Nausea | 12 | 0.5 (0.3, 0.9) | 1.9 | (1.0, 3.4) | 4 | 0.2 (0.0, 0.4) | 0.7 | (0.2, 1.8) |
| Oesophageal ulcer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Paraesthesia oral | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Parotid duct obstruction | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Vomiting | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| General disorders and administration site conditions | 455 | 18.6 (17.1, 20.2) | 72.9 | (66.4, 80.0) | 71 | 2.8 (2.2, 3.6) | 12.5 | (9.8, 15.8) |
| Asthenia | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Axillary pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Chest discomfort | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Chest pain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Chills | 99 | 4.1 (3.3, 4.9) | 15.9 | (12.9, 19.3) | 6 | 0.2 (0.1, 0.5) | 1.1 | (0.4, 2.3) |
| Drug withdrawal syndrome | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Fatigue | 166 | 6.8 (5.8, 7.9) | 26.6 | (22.7, 31.0) | 25 | 1.0 (0.6, 1.5) | 4.4 | (2.9, 6.5) |
| Feeling abnormal | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Feeling hot | 1 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Granuloma | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Injection site erythema | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site hypoaesthesia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site induration | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site irritation | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site lymphadenopathy | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Injection site oedema | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site pain | 271 | 11.1 (9.9, 12.4) | 43.4 | (38.4, 48.9) | 41 | 1.6 (1.2, 2.2) | 7.2 | (5.2, 9.8) |
| Injection site paraesthesia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site pruritus | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site swelling | 5 | 0.2 (0.1, 0.5) | 0.8 | (0.3, 1.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Injection site vesicles | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site warmth | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injury associated with device | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |

## 14.60. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Male

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2443, TE[b]=6.2) | | | | Placebo (N[a]=2500, TE[b]=5.7) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Malaise | 20 | 0.8 (0.5, 1.3) | 3.2 | (2.0, 5.0) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pain | 45 | 1.8 (1.3, 2.5) | 7.2 | (5.3, 9.7) | 6 | 0.2 (0.2, 0.5) | 1.1 | (0.4, 2.3) |
| Peripheral swelling | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Pyrexia | 93 | 3.8 (3.1, 4.6) | 14.9 | (12.0, 18.3) | 4 | 0.2 (0.0, 0.4) | 0.7 | (0.2, 1.8) |
| Sluggishness | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Swelling | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Vaccination site pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hepatobiliary disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Cholelithiasis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hepatic cirrhosis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Infections and infestations | 14 | 0.6 (0.3, 1.0) | 2.2 | (1.2, 3.8) | 11 | 0.4 (0.2, 0.8) | 1.9 | (1.0, 3.5) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Abscess | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Acute sinusitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Appendicitis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Appendicitis perforated | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Candida infection | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Cystitis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Device related infection | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Diverticulitis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Epididymitis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Herpes zoster | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hordeolum | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Infected dermal cyst | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Oral herpes | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Otitis externa | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Otitis media acute | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Peritonitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Rhinitis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Salmonellosis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Sepsis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Sinusitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Urinary tract infection | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |

## 14.60. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Male

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2443, TE[b]=6.2) | | | | Placebo (N[a]=2500, TE[b]=5.7) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Varicella zoster virus infection | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injury, poisoning and procedural complications | 14 | 0.6 (0.3, 1.0) | 2.2 | (1.2, 3.8) | 12 | 0.5 (0.2, 0.8) | 2.1 | (1.1, 3.7) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Animal bite | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Arthropod sting | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Bone contusion | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Cartilage injury | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Concussion | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Contusion | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Craniocerebral injury | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Fall | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.6) | 4 | 0.2 (0.0, 0.4) | 0.7 | (0.2, 1.8) |
| Hip fracture | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Humerus fracture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Ligament rupture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Ligament sprain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Limb crushing injury | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Limb injury | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Meniscus injury | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Muscle strain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Neck injury | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Road traffic accident | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Skin laceration | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Tendon rupture | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Investigations | 18 | 0.7 (0.4, 1.2) | 2.9 | (1.7, 4.6) | 8 | 0.3 (0.1, 0.6) | 1.4 | (0.6, 2.8) |
| Alpha 1 fetoprotein increased | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Blood cholesterol increased | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Blood pressure increased | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Body temperature increased | 16 | 0.7 (0.4, 1.1) | 2.6 | (1.5, 4.2) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Heart rate increased | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hepatic enzyme increased | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Lipase increased | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Prostatic specific antigen increased | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |

## 14.60. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Male

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2443, TE[b]=6.2) | | | | Placebo (N[a]=2500, TE[b]=5.7) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Respiratory rate increased | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Metabolism and nutrition disorders | 8 | 0.3 (0.1, 0.6) | 1.3 | (0.6, 2.5) | 9 | 0.4 (0.2, 0.7) | 1.6 | (0.7, 3.0) |
| Decreased appetite | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Dehydration | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Diabetes mellitus | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Diabetic ketoacidosis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Gout | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 4 | 0.2 (0.0, 0.4) | 0.7 | (0.2, 1.8) |
| Hypercholesterolaemia | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hypokalaemia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hyponatraemia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Type 2 diabetes mellitus | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Vitamin D deficiency | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Musculoskeletal and connective tissue disorders | 151 | 6.2 (5.3, 7.2) | 24.2 | (20.5, 28.4) | 18 | 0.7 (0.4, 1.1) | 3.2 | (1.9, 5.0) |
| Arthralgia | 19 | 0.8 (0.5, 1.2) | 3.0 | (1.8, 4.8) | 4 | 0.2 (0.0, 0.4) | 0.7 | (0.2, 1.8) |
| Arthritis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Back pain | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Bone pain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Joint effusion | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Joint stiffness | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Muscular weakness | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Musculoskeletal chest pain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Musculoskeletal stiffness | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Myalgia | 106 | 4.3 (3.6, 5.2) | 17.0 | (13.9, 20.6) | 8 | 0.3 (0.1, 0.6) | 1.4 | (0.6, 2.8) |
| Neck pain | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pain in extremity | 22 | 0.9 (0.6, 1.4) | 3.5 | (2.2, 5.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Rotator cuff syndrome | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Spinal stenosis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Synovial cyst | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 6 | 0.2 (0.1, 0.5) | 1.0 | (0.4, 2.1) | 7 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.5) |
| Basal cell carcinoma | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |

## 14.60. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Male

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2443, TE[b]=6.2) | | | | Placebo (N[a]=2500, TE[b]=5.7) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Granular cell tumour | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Malignant melanoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Prostate cancer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Skin cancer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Squamous cell carcinoma of skin | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Nervous system disorders | 107 | 4.4 (3.6, 5.3) | 17.2 | (14.1, 20.7) | 29 | 1.2 (0.8, 1.7) | 5.1 | (3.4, 7.3) |
| Altered state of consciousness | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Bell's palsy | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Cerebrovascular accident | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Cervicobrachial syndrome | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Dizziness | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Headache | 91 | 3.7 (3.0, 4.6) | 14.6 | (11.7, 17.9) | 19 | 0.8 (0.5, 1.2) | 3.4 | (2.0, 5.2) |
| Hyperaesthesia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hypoaesthesia | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Lethargy | 7 | 0.3 (0.1, 0.6) | 1.1 | (0.5, 2.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Migraine | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Nerve compression | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Neuralgic amyotrophy | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Paraesthesia | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Sciatica | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Syncope | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Tension headache | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Tremor | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Psychiatric disorders | 10 | 0.4 (0.2, 0.8) | 1.6 | (0.8, 2.9) | 8 | 0.3 (0.1, 0.6) | 1.4 | (0.6, 2.8) |
| Abnormal dreams | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Alcoholism | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Anxiety | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) |

## 14.60. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Male

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2443, TE[b]=6.2) | | | | Placebo (N[a]=2500, TE[b]=5.7) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Attention deficit hyperactivity disorder | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Depression | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Generalised anxiety disorder | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Insomnia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Mood altered | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Nightmare | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Poor quality sleep | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Renal and urinary disorders | 7 | 0.3 (0.1, 0.6) | 1.1 | (0.5, 2.3) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Cystitis haemorrhagic | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Haematuria | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Nephrolithiasis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Renal colic | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Renal cyst | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Urinary incontinence | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Reproductive system and breast disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Prostatitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Scrotal disorder | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Respiratory, thoracic and mediastinal disorders | 7 | 0.3 (0.1, 0.6) | 1.1 | (0.5, 2.3) | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.1) |
| Asthma | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Epistaxis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Nasal congestion | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Pharyngeal swelling | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Respiratory failure | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Rhinorrhoea | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Throat tightness | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Skin and subcutaneous tissue disorders | 11 | 0.5 (0.2, 0.8) | 1.8 | (0.9, 3.2) | 4 | 0.2 (0.0, 0.4) | 0.7 | (0.2, 1.8) |
| Alopecia areata | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Cold sweat | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Dermal cyst | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Erythema | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |

## 14.60. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Male

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2443, TE[b]=6.2) | | | | Placebo (N[a]=2500, TE[b]=5.7) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Hyperhidrosis | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Night sweats | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Pruritus | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Psoriasis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Rash | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Rash papular | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Urticaria | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Xanthoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Surgical and medical procedures | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Bunion operation | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Vascular disorders | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.6) | 6 | 0.2 (0.1, 0.5) | 1.1 | (0.4, 2.3) |
| Deep vein thrombosis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Flushing | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Haematoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hot flush | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hypertension | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:24)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ub3IA/C4591031_A_SBLA/adae_s131_sex_6m_saf

## 14.61. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | | Placebo (N[a]=2520, TE[b]=5.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 767 | 29.4 (27.6, 31.2) | 112.7 | (104.9, 121.0) | 236 | 9.4 (8.3, 10.6) | 42.0 | (36.8, 47.7) |
| Blood and lymphatic system disorders | 94 | 3.6 (2.9, 4.4) | 13.8 | (11.2, 16.9) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Anaemia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Iron deficiency anaemia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Lymph node pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Lymphadenopathy | 91 | 3.5 (2.8, 4.3) | 13.4 | (10.8, 16.4) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Lymphocytosis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Lymphopenia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Neutropenia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Thrombocytopenia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Cardiac disorders | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Acute myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Atrial fibrillation | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Cardiac failure | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Myocardial infarction | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Palpitations | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Pericarditis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Tachycardia | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Congenital, familial and genetic disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Thalassaemia beta | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Ear and labyrinth disorders | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Ear pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Vertigo | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Endocrine disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Goitre | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hypothyroidism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Thyroid cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Thyroid mass | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Eye disorders | 11 | 0.4 (0.2, 0.8) | 1.6 | (0.8, 2.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Cataract | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Chalazion | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |

## 14.61. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | | Placebo (N[a]=2520, TE[b]=5.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Diplopia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Dry age-related macular degeneration | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Dry eye | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Eye pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Eyelid ptosis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Glaucoma | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Keratitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Macular degeneration | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Ocular hyperaemia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Photophobia | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Vitreous detachment | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Gastrointestinal disorders | 57 | 2.2 (1.7, 2.8) | 8.4 | (6.3, 10.9) | 31 | 1.2 (0.8, 1.7) | 5.5 | (3.7, 7.8) |
| Abdominal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Abdominal pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Abdominal pain upper | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Constipation | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Diarrhoea | 12 | 0.5 (0.2, 0.8) | 1.8 | (0.9, 3.1) | 9 | 0.4 (0.2, 0.7) | 1.6 | (0.7, 3.0) |
| Diverticulum | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Dyspepsia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Gastrooesophageal reflux disease | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 4 | 0.2 (0.0, 0.4) | 0.7 | (0.2, 1.8) |
| Hypoaesthesia teeth | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Nausea | 39 | 1.5 (1.1, 2.0) | 5.7 | (4.1, 7.8) | 13 | 0.5 (0.3, 0.9) | 2.3 | (1.2, 4.0) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Toothache | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Vomiting | 10 | 0.4 (0.2, 0.7) | 1.5 | (0.7, 2.7) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| General disorders and administration site conditions | 628 | 24.0 (22.4, 25.7) | 92.3 | (85.2, 99.8) | 92 | 3.7 (3.0, 4.5) | 16.4 | (13.2, 20.1) |
| Asthenia | 5 | 0.2 (0.1, 0.4) | 0.7 | (0.2, 1.7) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Axillary pain | 11 | 0.4 (0.2, 0.8) | 1.6 | (0.8, 2.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Chest discomfort | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Chest pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Chills | 138 | 5.3 (4.5, 6.2) | 20.3 | (17.0, 24.0) | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.1) |
| Cyst | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |

## 14.61. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | | Placebo (N[a]=2520, TE[b]=5.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Fatigue | 207 | 7.9 (6.9, 9.0) | 30.4 | (26.4, 34.9) | 39 | 1.5 (1.1, 2.1) | 6.9 | (4.9, 9.5) |
| Feeling abnormal | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Feeling hot | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site bruising | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.3) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Injection site discomfort | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site erythema | 19 | 0.7 (0.4, 1.1) | 2.8 | (1.7, 4.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site induration | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site inflammation | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site oedema | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site pain | 386 | 14.8 (13.4, 16.2) | 56.7 | (51.2, 62.7) | 39 | 1.5 (1.1, 2.1) | 6.9 | (4.9, 9.5) |
| Injection site pruritus | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site rash | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site reaction | 5 | 0.2 (0.1, 0.4) | 0.7 | (0.2, 1.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site swelling | 16 | 0.6 (0.4, 1.0) | 2.4 | (1.3, 3.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injection site warmth | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Malaise | 15 | 0.6 (0.3, 0.9) | 2.2 | (1.2, 3.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Metaplasia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pain | 92 | 3.5 (2.8, 4.3) | 13.5 | (10.9, 16.6) | 11 | 0.4 (0.2, 0.8) | 2.0 | (1.0, 3.5) |
| Peripheral swelling | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Pyrexia | 158 | 6.0 (5.2, 7.0) | 23.2 | (19.7, 27.1) | 4 | 0.2 (0.0, 0.4) | 0.7 | (0.2, 1.8) |
| Swelling | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Vaccination site rash | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hepatobiliary disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Bile duct stone | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Cholelithiasis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hepatic steatosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Immune system disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Allergic oedema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Allergy to arthropod sting | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Food allergy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Seasonal allergy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Infections and infestations | 22 | 0.8 (0.5, 1.3) | 3.2 | (2.0, 4.9) | 32 | 1.3 (0.9, 1.8) | 5.7 | (3.9, 8.0) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |

## 14.61. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | | Placebo (N[a]=2520, TE[b]=5.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Acute sinusitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Adenoiditis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Appendicitis perforated | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Arthritis infective | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Candida infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Cellulitis | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Conjunctivitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Conjunctivitis bacterial | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Cystitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Diverticulitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Ear infection | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Empyema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Eye infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Groin abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hand-foot-and-mouth disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Helicobacter infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Herpes zoster | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hordeolum | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Kidney infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Latent tuberculosis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Mastitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Onychomycosis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Otitis externa | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Otitis media | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Septic shock | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Sinusitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Tooth abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Tooth infection | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Urinary tract infection | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 7 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.6) |
| Vestibular neuronitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Vulvovaginal mycotic infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Injury, poisoning and procedural complications | 10 | 0.4 (0.2, 0.7) | 1.5 | (0.7, 2.7) | 24 | 1.0 (0.6, 1.4) | 4.3 | (2.7, 6.4) |
| Ankle fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |

## 14.61. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | | Placebo (N[a]=2520, TE[b]=5.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Arthropod sting | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Burns third degree | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Contusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Corneal abrasion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Exposure during pregnancy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Fall | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 6 | 0.2 (0.1, 0.5) | 1.1 | (0.4, 2.3) |
| Head injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Humerus fracture | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Joint injury | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Ligament sprain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Limb injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Meniscus injury | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Muscle strain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Musculoskeletal injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Periorbital haemorrhage | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Post procedural haemorrhage | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Procedural pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Road traffic accident | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Skin abrasion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Skin laceration | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Stoma complication | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Stress fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Tibia fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Tooth fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Wrist fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Investigations | 17 | 0.7 (0.4, 1.0) | 2.5 | (1.5, 4.0) | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.1) |
| Antinuclear antibody positive | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Blood creatinine increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Blood glucose increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Body temperature increased | 14 | 0.5 (0.3, 0.9) | 2.1 | (1.1, 3.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hepatic enzyme increased | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |

## 14.61. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | | Placebo (N[a]=2520, TE[b]=5.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Inflammatory marker increased | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Metabolism and nutrition disorders | 12 | 0.5 (0.2, 0.8) | 1.8 | (0.9, 3.1) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Decreased appetite | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 1.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Dehydration | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Glucose tolerance impaired | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hypercholesterolaemia | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Iron deficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Type 2 diabetes mellitus | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Vitamin D deficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Musculoskeletal and connective tissue disorders | 204 | 7.8 (6.8, 8.9) | 30.0 | (26.0, 34.4) | 37 | 1.5 (1.0, 2.0) | 6.6 | (4.6, 9.1) |
| Arthralgia | 23 | 0.9 (0.6, 1.3) | 3.4 | (2.1, 5.1) | 12 | 0.5 (0.2, 0.8) | 2.1 | (1.1, 3.7) |
| Arthritis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Back pain | 5 | 0.2 (0.1, 0.4) | 0.7 | (0.2, 1.7) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Bone cyst | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Foot deformity | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Groin pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Joint swelling | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Metatarsalgia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Muscle fatigue | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Muscle swelling | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Musculoskeletal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Musculoskeletal pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Musculoskeletal stiffness | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Myalgia | 135 | 5.2 (4.4, 6.1) | 19.8 | (16.6, 23.5) | 12 | 0.5 (0.2, 0.8) | 2.1 | (1.1, 3.7) |
| Neck pain | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 1.9) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Osteoporosis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Pain in extremity | 35 | 1.3 (0.9, 1.9) | 5.1 | (3.6, 7.2) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Pain in jaw | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Plantar fasciitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |

## 14.61. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | | Placebo (N[a]=2520, TE[b]=5.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Psoriatic arthropathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Scoliosis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Synovial cyst | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Tendonitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Trigger finger | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 9 | 0.3 (0.2, 0.7) | 1.3 | (0.6, 2.5) | 4 | 0.2 (0.0, 0.4) | 0.7 | (0.2, 1.8) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Basal cell carcinoma | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Benign neoplasm of thyroid gland | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Breast cancer | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Focal nodular hyperplasia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Malignant melanoma | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Melanocytic naevus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Squamous cell carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Squamous cell carcinoma of skin | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Uterine leiomyoma | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Nervous system disorders | 190 | 7.3 (6.3, 8.3) | 27.9 | (24.1, 32.2) | 40 | 1.6 (1.1, 2.2) | 7.1 | (5.1, 9.7) |
| Carpal tunnel syndrome | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Cervical radiculopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Dizziness | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 1.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Dysgeusia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Headache | 169 | 6.5 (5.6, 7.5) | 24.8 | (21.2, 28.9) | 32 | 1.3 (0.9, 1.8) | 5.7 | (3.9, 8.0) |
| Hyperaesthesia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hypotonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |

## 14.61. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | | Placebo (N[a]=2520, TE[b]=5.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Lethargy | 5 | 0.2 (0.1, 0.4) | 0.7 | (0.2, 1.7) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Migraine | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Migraine with aura | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Paraesthesia | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Parosmia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Seizure | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Somnolence | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Syncope | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Taste disorder | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Pregnancy, puerperium and perinatal conditions | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Abortion spontaneous | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pregnancy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Psychiatric disorders | 7 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.1) | 7 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.6) |
| Adjustment disorder with mixed anxiety and depressed mood | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Anxiety | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Attention deficit hyperactivity disorder | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Depression | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Insomnia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Stress | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Renal and urinary disorders | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Dysuria | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Renal cyst | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Stress urinary incontinence | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Reproductive system and breast disorders | 8 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.3) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Atrophic vulvovaginitis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Breast calcifications | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Breast pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |

## 14.61. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | | Placebo (N[a]=2520, TE[b]=5.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Endometriosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Heavy menstrual bleeding | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Intermenstrual bleeding | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Menstruation irregular | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Ovarian cyst | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Respiratory, thoracic and mediastinal disorders | 8 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.3) | 12 | 0.5 (0.2, 0.8) | 2.1 | (1.1, 3.7) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Asthma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Asthma exercise induced | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Dry throat | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Epistaxis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Nasal congestion | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Nasal polyps | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pleural effusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pleurisy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pulmonary congestion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Rhinorrhoea | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Sinus congestion | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Sleep apnoea syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Sneezing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Skin and subcutaneous tissue disorders | 14 | 0.5 (0.3, 0.9) | 2.1 | (1.1, 3.5) | 8 | 0.3 (0.1, 0.6) | 1.4 | (0.6, 2.8) |
| Alopecia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Dermal cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Dermatitis allergic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Dermatitis contact | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Dry skin | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hyperhidrosis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Intertrigo | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Night sweats | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Pruritus | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Rash | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |

## 14.61. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | | Placebo (N[a]=2520, TE[b]=5.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Rash erythematous | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Urticaria | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Surgical and medical procedures | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Abortion induced | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Gastrectomy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Vascular disorders | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.3) | 6 | 0.2 (0.1, 0.5) | 1.1 | (0.4, 2.3) |
| Flushing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hot flush | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hypertension | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Hypotension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Peripheral venous disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:24)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_sex_6m_saf

## 14.62. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 996 | 25.0 (23.6, 26.4) | 98.9 | (92.8, 105.2) | 303 | 7.6 (6.8, 8.5) | 34.4 | (30.6, 38.4) |
| Blood and lymphatic system disorders | 100 | 2.5 (2.0, 3.0) | 9.9 | (8.1, 12.1) | 4 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.2) |
| Anaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Iron deficiency anaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lymph node pain | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lymphadenitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lymphadenopathy | 97 | 2.4 (2.0, 3.0) | 9.6 | (7.8, 11.7) | 4 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.2) |
| Cardiac disorders | 12 | 0.3 (0.2, 0.5) | 1.2 | (0.6, 2.1) | 5 | 0.1 (0.0, 0.3) | 0.6 | (0.2, 1.3) |
| Acute myocardial infarction | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Atrial fibrillation | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Atrial flutter | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Cardiac failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Coronary artery insufficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Palpitations | 4 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Tachycardia | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ear and labyrinth disorders | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Ear pain | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Tinnitus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Vertigo | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vertigo positional | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Endocrine disorders | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 4 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.2) |
| Goitre | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hypothyroidism | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Thyroid cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Eye disorders | 8 | 0.2 (0.1, 0.4) | 0.8 | (0.3, 1.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Chalazion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Diplopia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dry eye | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Eye pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Eyelid ptosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Glaucoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |

## 14.62. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Keratitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Macular degeneration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ocular hyperaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Photophobia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Gastrointestinal disorders | 73 | 1.8 (1.4, 2.3) | 7.2 | (5.7, 9.1) | 39 | 1.0 (0.7, 1.3) | 4.4 | (3.1, 6.0) |
| Abdominal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Abdominal pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Abdominal pain upper | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 4 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.2) |
| Aphthous ulcer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ascites | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Constipation | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dental caries | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dental cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Diarrhoea | 18 | 0.5 (0.3, 0.7) | 1.8 | (1.1, 2.8) | 10 | 0.3 (0.1, 0.5) | 1.1 | (0.5, 2.1) |
| Diverticulum | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dry mouth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dyspepsia | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Gastric fistula | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Gastrooesophageal reflux disease | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 5 | 0.1 (0.0, 0.3) | 0.6 | (0.2, 1.3) |
| Gingival pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Haemorrhoids | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hypoaesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hypoaesthesia teeth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Inguinal hernia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nausea | 42 | 1.1 (0.8, 1.4) | 4.2 | (3.0, 5.6) | 15 | 0.4 (0.2, 0.6) | 1.7 | (1.0, 2.8) |
| Oesophageal ulcer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Paraesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Parotid duct obstruction | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Toothache | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Vomiting | 10 | 0.3 (0.1, 0.5) | 1.0 | (0.5, 1.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| General disorders and administration site conditions | 796 | 20.0 (18.7, 21.2) | 79.0 | (73.6, 84.7) | 114 | 2.9 (2.4, 3.4) | 12.9 | (10.7, 15.5) |
| Asthenia | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.62. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Axillary pain | 10 | 0.3 (0.1, 0.5) | 1.0 | (0.5, 1.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Chest discomfort | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Chest pain | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Chills | 173 | 4.3 (3.7, 5.0) | 17.2 | (14.7, 19.9) | 7 | 0.2 (0.1, 0.4) | 0.8 | (0.3, 1.6) |
| Cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Fatigue | 281 | 7.0 (6.3, 7.9) | 27.9 | (24.7, 31.4) | 48 | 1.2 (0.9, 1.6) | 5.4 | (4.0, 7.2) |
| Feeling abnormal | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Feeling hot | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site bruising | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Injection site discomfort | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site erythema | 19 | 0.5 (0.3, 0.7) | 1.9 | (1.1, 2.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site hypoaesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site inflammation | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site irritation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site lymphadenopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Injection site oedema | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site pain | 464 | 11.6 (10.7, 12.7) | 46.1 | (42.0, 50.5) | 51 | 1.3 (1.0, 1.7) | 5.8 | (4.3, 7.6) |
| Injection site pruritus | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site reaction | 4 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site swelling | 17 | 0.4 (0.2, 0.7) | 1.7 | (1.0, 2.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site vesicles | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site warmth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Malaise | 27 | 0.7 (0.4, 1.0) | 2.7 | (1.8, 3.9) | 4 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.2) |
| Metaplasia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pain | 117 | 2.9 (2.4, 3.5) | 11.6 | (9.6, 13.9) | 13 | 0.3 (0.2, 0.6) | 1.5 | (0.8, 2.5) |
| Peripheral swelling | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Pyrexia | 189 | 4.7 (4.1, 5.4) | 18.8 | (16.2, 21.6) | 5 | 0.1 (0.0, 0.3) | 0.6 | (0.2, 1.3) |
| Sluggishness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Swelling | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vaccination site pain | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vaccination site rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hepatobiliary disorders | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 4 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.2) |
| Bile duct stone | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Cholelithiasis | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hepatic cirrhosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hepatic steatosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.62. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Immune system disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Allergy to arthropod sting | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Food allergy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Seasonal allergy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Infections and infestations | 32 | 0.8 (0.5, 1.1) | 3.2 | (2.2, 4.5) | 37 | 0.9 (0.7, 1.3) | 4.2 | (3.0, 5.8) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Abscess | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Acute sinusitis | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Adenoiditis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Appendicitis | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Appendicitis perforated | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Arthritis infective | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Candida infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Cellulitis | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Conjunctivitis bacterial | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cystitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Device related infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Diverticulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ear infection | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Empyema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Epididymitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Eye infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Groin abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hand-foot-and-mouth disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Herpes zoster | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hordeolum | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Infected dermal cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Kidney infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Mastitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Onychomycosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Oral herpes | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Otitis externa | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Otitis media | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Otitis media acute | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Peritonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Rhinitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.62. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Salmonellosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Sepsis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Sinusitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Tooth abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tooth infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Urinary tract infection | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 8 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.8) |
| Varicella zoster virus infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vestibular neuronitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vulvovaginal mycotic infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Injury, poisoning and procedural complications | 14 | 0.4 (0.2, 0.6) | 1.4 | (0.8, 2.3) | 31 | 0.8 (0.5, 1.1) | 3.5 | (2.4, 5.0) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Animal bite | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ankle fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Arthropod sting | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Burns third degree | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cartilage injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Concussion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Contusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Craniocerebral injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Fall | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 9 | 0.2 (0.1, 0.4) | 1.0 | (0.5, 1.9) |
| Head injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hip fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Humerus fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ligament rupture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ligament sprain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Limb crushing injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Limb injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Meniscus injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Muscle strain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Musculoskeletal injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Neck injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Post procedural haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Procedural pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Road traffic accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.62. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Skin abrasion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Skin laceration | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Stress fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tibia fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tooth fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Wrist fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Investigations | 30 | 0.8 (0.5, 1.1) | 3.0 | (2.0, 4.3) | 9 | 0.2 (0.1, 0.4) | 1.0 | (0.5, 1.9) |
| Alpha 1 foetoprotein increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Antinuclear antibody positive | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Blood cholesterol increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Blood creatinine increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Blood pressure increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Body temperature increased | 26 | 0.7 (0.4, 1.0) | 2.6 | (1.7, 3.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Heart rate increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hepatic enzyme increased | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Lipase increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Prostatic specific antigen increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Respiratory rate increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Metabolism and nutrition disorders | 14 | 0.4 (0.2, 0.6) | 1.4 | (0.8, 2.3) | 11 | 0.3 (0.1, 0.5) | 1.2 | (0.6, 2.2) |
| Decreased appetite | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dehydration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Diabetes mellitus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Diabetic ketoacidosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Gout | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 4 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.2) |
| Hypercholesterolaemia | 4 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hypokalaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hyponatraemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Iron deficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Type 2 diabetes mellitus | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vitamin D deficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Musculoskeletal and connective tissue disorders | 269 | 6.7 (6.0, 7.6) | 26.7 | (23.6, 30.1) | 40 | 1.0 (0.7, 1.4) | 4.5 | (3.2, 6.2) |
| Arthralgia | 31 | 0.8 (0.5, 1.1) | 3.1 | (2.1, 4.4) | 11 | 0.3 (0.1, 0.5) | 1.2 | (0.6, 2.2) |

## 14.62. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Arthritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Back pain | 7 | 0.2 (0.1, 0.4) | 0.7 | (0.3, 1.4) | 4 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.2) |
| Bone cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Bone pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Foot deformity | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Groin pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Joint effusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Joint stiffness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Joint swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Metatarsalgia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Muscle fatigue | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Muscle swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Muscular weakness | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Musculoskeletal chest pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Musculoskeletal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Musculoskeletal pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Musculoskeletal stiffness | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Myalgia | 179 | 4.5 (3.9, 5.2) | 17.8 | (15.3, 20.6) | 13 | 0.3 (0.2, 0.6) | 1.5 | (0.8, 2.5) |
| Neck pain | 8 | 0.2 (0.1, 0.4) | 0.8 | (0.3, 1.6) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Osteoporosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pain in extremity | 49 | 1.2 (0.9, 1.6) | 4.9 | (3.6, 6.4) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Pain in jaw | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Plantar fasciitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Psoriatic arthropathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Rotator cuff syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Scoliosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Spinal stenosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Synovial cyst | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Tendonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Trigger finger | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 13 | 0.3 (0.2, 0.6) | 1.3 | (0.7, 2.2) | 11 | 0.3 (0.1, 0.5) | 1.2 | (0.6, 2.2) |

## 14.62. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Basal cell carcinoma | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Benign neoplasm of thyroid gland | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Breast cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Focal nodular hyperplasia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Granular cell tumour | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Malignant melanoma | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Melanocytic naevus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Prostate cancer | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Skin cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Squamous cell carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Squamous cell carcinoma of skin | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Nervous system disorders | 220 | 5.5 (4.8, 6.3) | 21.8 | (19.0, 24.9) | 53 | 1.3 (1.0, 1.7) | 6.0 | (4.5, 7.9) |
| Altered state of consciousness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Bell's palsy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Carpal tunnel syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cervical radiculopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Cervicobrachial syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dizziness | 8 | 0.2 (0.1, 0.4) | 0.8 | (0.3, 1.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Dysgeusia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Headache | 191 | 4.8 (4.1, 5.5) | 19.0 | (16.4, 21.8) | 40 | 1.0 (0.7, 1.4) | 4.5 | (3.2, 6.2) |
| Hyperaesthesia | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hypoaesthesia | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.62. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Lethargy | 9 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Migraine | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Migraine with aura | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nerve compression | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Neuralgic amyotrophy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Paraesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Parosmia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Sciatica | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Syncope | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Taste disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pregnancy, puerperium and perinatal conditions | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Abortion spontaneous | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pregnancy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Psychiatric disorders | 15 | 0.4 (0.2, 0.6) | 1.5 | (0.8, 2.5) | 11 | 0.3 (0.1, 0.5) | 1.2 | (0.6, 2.2) |
| Abnormal dreams | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Adjustment disorder with mixed anxiety and depressed mood | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Alcoholism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Anxiety | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 4 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.2) |
| Attention deficit hyperactivity disorder | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Depression | 4 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.0) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Generalised anxiety disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Insomnia | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Mood altered | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Poor quality sleep | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Stress | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Renal and urinary disorders | 10 | 0.3 (0.1, 0.5) | 1.0 | (0.5, 1.8) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Cystitis haemorrhagic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dysuria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Haematuria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nephrolithiasis | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |

## 14.62. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Renal colic | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Renal cyst | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Stress urinary incontinence | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Urinary incontinence | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Reproductive system and breast disorders | 6 | 0.2 (0.1, 0.3) | 0.6 | (0.2, 1.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Atrophic vulvovaginitis | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Breast calcifications | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intermenstrual bleeding | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ovarian cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Prostatitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Scrotal disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Respiratory, thoracic and mediastinal disorders | 12 | 0.3 (0.2, 0.5) | 1.2 | (0.6, 2.1) | 14 | 0.4 (0.2, 0.6) | 1.6 | (0.9, 2.7) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Asthma | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Epistaxis | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nasal congestion | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Nasal polyps | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pharyngeal swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pleural effusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pleurisy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pulmonary congestion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Rhinorrhoea | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Sinus congestion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Sleep apnoea syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Sneezing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Throat tightness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Skin and subcutaneous tissue disorders | 22 | 0.6 (0.3, 0.8) | 2.2 | (1.4, 3.3) | 11 | 0.3 (0.1, 0.5) | 1.2 | (0.6, 2.2) |
| Alopecia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Alopecia areata | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cold sweat | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dermal cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Dermatitis contact | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dry skin | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |

## 14.62. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Erythema | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hyperhidrosis | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intertrigo | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Night sweats | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pruritus | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Psoriasis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Rash | 4 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.0) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Rash papular | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Urticaria | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Xanthoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Surgical and medical procedures | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Bunion operation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Gastrectomy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vascular disorders | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) | 10 | 0.3 (0.1, 0.5) | 1.1 | (0.5, 2.1) |
| Deep vein thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Flushing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Haematoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hot flush | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Hypertension | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Hypotension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Peripheral venous disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

Note: MedDRA (v24.1) coding dictionary applied.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:22)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_race_6m_saf

## 14.63. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: Black or African American

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=457, TE[b]=1.4) | | | | Placebo (N[a]=447, TE[b]=1.1) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 115 | 25.2 (21.2, 29.4) | 84.8 | (70.0, 101.8) | 36 | 8.1 (5.7, 11.0) | 32.5 | (22.8, 45.1) |
| Blood and lymphatic system disorders | 14 | 3.1 (1.7, 5.1) | 10.3 | (5.6, 17.3) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Lymph node pain | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Lymphadenopathy | 13 | 2.8 (1.5, 4.8) | 9.6 | (5.1, 16.4) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Cardiac disorders | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 2 | 0.4 (0.1, 1.6) | 1.8 | (0.2, 6.5) |
| Myocardial infarction | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Palpitations | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Pericarditis | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Endocrine disorders | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Thyroid mass | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Gastrointestinal disorders | 7 | 1.5 (0.6, 3.1) | 5.2 | (2.1, 10.6) | 4 | 0.9 (0.2, 2.3) | 3.6 | (1.0, 9.3) |
| Abdominal pain | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Abdominal pain upper | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Diarrhoea | 3 | 0.7 (0.1, 1.9) | 2.2 | (0.5, 6.5) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Nausea | 3 | 0.7 (0.1, 1.9) | 2.2 | (0.5, 6.5) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Toothache | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Vomiting | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| General disorders and administration site conditions | 93 | 20.4 (16.8, 24.3) | 68.6 | (55.4, 84.0) | 18 | 4.0 (2.4, 6.3) | 16.3 | (9.6, 25.7) |
| Asthenia | 2 | 0.4 (0.1, 1.6) | 1.5 | (0.2, 5.3) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Chills | 23 | 5.0 (3.2, 7.5) | 17.0 | (10.8, 25.5) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Fatigue | 21 | 4.6 (2.9, 6.9) | 15.5 | (9.6, 23.7) | 6 | 1.3 (0.5, 2.9) | 5.4 | (2.0, 11.8) |
| Feeling hot | 2 | 0.4 (0.1, 1.6) | 1.5 | (0.2, 5.3) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Granuloma | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Injection site erythema | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Injection site induration | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Injection site inflammation | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Injection site pain | 64 | 14.0 (11.0, 17.5) | 47.2 | (36.4, 60.3) | 12 | 2.7 (1.4, 4.6) | 10.8 | (5.6, 19.0) |
| Injection site swelling | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Malaise | 3 | 0.7 (0.1, 1.9) | 2.2 | (0.5, 6.5) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Pain | 5 | 1.1 (0.4, 2.5) | 3.7 | (1.2, 8.6) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Pyrexia | 20 | 4.4 (2.7, 6.7) | 14.8 | (9.0, 22.8) | 2 | 0.4 (0.1, 1.6) | 1.8 | (0.2, 6.5) |
| Infections and infestations | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |

## 14.63. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: Black or African American

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=457, TE[b]=1.4) | | | | Placebo (N[a]=447, TE[b]=1.1) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Urinary tract infection | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Injury, poisoning and procedural complications | 2 | 0.4 (0.1, 1.6) | 1.5 | (0.2, 5.3) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Ankle fracture | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Humerus fracture | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Meniscus injury | 2 | 0.4 (0.1, 1.6) | 1.5 | (0.2, 5.3) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Investigations | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 2 | 0.4 (0.1, 1.6) | 1.8 | (0.2, 6.5) |
| Body temperature increased | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Prostatic specific antigen increased | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Metabolism and nutrition disorders | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Type 2 diabetes mellitus | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Musculoskeletal and connective tissue disorders | 30 | 6.6 (4.5, 9.2) | 22.1 | (14.9, 31.6) | 5 | 1.1 (0.4, 2.6) | 4.5 | (1.5, 10.5) |
| Arthralgia | 4 | 0.9 (0.2, 2.2) | 3.0 | (0.8, 7.6) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Back pain | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Musculoskeletal pain | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Myalgia | 19 | 4.2 (2.5, 6.4) | 14.0 | (8.4, 21.9) | 2 | 0.4 (0.1, 1.6) | 1.8 | (0.2, 6.5) |
| Osteoarthritis | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Pain in extremity | 4 | 0.9 (0.2, 2.2) | 3.0 | (0.8, 7.6) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Synovial cyst | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Prostate cancer | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Nervous system disorders | 24 | 5.3 (3.4, 7.7) | 17.7 | (11.3, 26.3) | 9 | 2.0 (0.9, 3.8) | 8.1 | (3.7, 15.4) |
| Cerebrovascular accident | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Headache | 21 | 4.6 (2.9, 6.9) | 15.5 | (9.6, 23.7) | 6 | 1.3 (0.5, 2.9) | 5.4 | (2.0, 11.8) |
| Hypotonia | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Lethargy | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Migraine | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Somnolence | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Syncope | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Psychiatric disorders | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Depression | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Renal and urinary disorders | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |

## 14.63. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: Black or African American

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=457, TE[b]=1.4) | | | | Placebo (N[a]=447, TE[b]=1.1) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Urinary incontinence | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 2 | 0.4 (0.1, 1.6) | 1.8 | (0.2, 6.5) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Nasal congestion | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Respiratory failure | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Sinus congestion | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Skin and subcutaneous tissue disorders | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Pruritus | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Vascular disorders | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 2 | 0.4 (0.1, 1.6) | 1.8 | (0.2, 6.5) |
| Hypertension | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Peripheral venous disease | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |

Note: MedDRA (v24.1) coding dictionary applied.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:22)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File:
./nda2 ubBLA/C4591031 A SBLA/adae s131 race 6m saf

## 14.64. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: All Others

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=612, TE[b]=1.6) | | | | Placebo (N[a]=580, TE[b]=1.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 224 | 36.6 (32.8, 40.6) | 138.7 | (121.1, 158.1) | 55 | 9.5 (7.2, 12.2) | 40.4 | (30.4, 52.5) |
| Blood and lymphatic system disorders | 28 | 4.6 (3.1, 6.5) | 17.3 | (11.5, 25.1) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Lymph node pain | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Lymphadenitis | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Lymphadenopathy | 25 | 4.1 (2.7, 6.0) | 15.5 | (10.0, 22.8) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Lymphocytosis | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Lymphopenia | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Neutropenia | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Thrombocytopenia | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Cardiac disorders | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Supraventricular tachycardia | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Congenital, familial and genetic disorders | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Thalassaemia beta | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Ear and labyrinth disorders | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Vertigo | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Eye disorders | 3 | 0.5 (0.1, 1.4) | 1.9 | (0.4, 5.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Cataract | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Dry age-related macular degeneration | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Photophobia | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Vitreous detachment | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Gastrointestinal disorders | 12 | 2.0 (1.0, 3.4) | 7.4 | (3.8, 13.0) | 4 | 0.7 (0.2, 1.8) | 2.9 | (0.8, 7.5) |
| Abdominal pain | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Diarrhoea | 5 | 0.8 (0.3, 1.9) | 3.1 | (1.0, 7.2) | 2 | 0.3 (0.0, 1.2) | 1.5 | (0.2, 5.3) |
| Dyspepsia | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Gastrooesophageal reflux disease | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Nausea | 6 | 1.0 (0.4, 2.1) | 3.7 | (1.4, 8.1) | 2 | 0.3 (0.0, 1.2) | 1.5 | (0.2, 5.3) |
| Vomiting | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| General disorders and administration site conditions | 194 | 31.7 (28.0, 35.5) | 120.1 | (103.8, 138.2) | 31 | 5.3 (3.7, 7.5) | 22.7 | (15.5, 32.3) |
| Asthenia | 3 | 0.5 (0.1, 1.4) | 1.9 | (0.4, 5.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Axillary pain | 3 | 0.5 (0.1, 1.4) | 1.9 | (0.4, 5.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |

## 14.64. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: All Others

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=612, TE[b]=1.6) | | | | Placebo (N[a]=580, TE[b]=1.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Chills | 41 | 6.7 (4.9, 9.0) | 25.4 | (18.2, 34.4) | 4 | 0.7 (0.2, 1.8) | 2.9 | (0.8, 7.5) |
| Drug withdrawal syndrome | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Fatigue | 71 | 11.6 (9.2, 14.4) | 44.0 | (34.3, 55.4) | 10 | 1.7 (0.8, 3.1) | 7.3 | (3.5, 13.5) |
| Injection site erythema | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Injection site induration | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Injection site pain | 129 | 21.1 (17.9, 24.5) | 79.9 | (66.7, 94.9) | 17 | 2.9 (1.7, 4.7) | 12.5 | (7.3, 20.0) |
| Injection site paraesthesia | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Injection site pruritus | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Injection site rash | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Injection site reaction | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Injection site swelling | 3 | 0.5 (0.1, 1.4) | 1.9 | (0.4, 5.4) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Injury associated with device | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Malaise | 5 | 0.8 (0.3, 1.9) | 3.1 | (1.0, 7.2) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Pain | 15 | 2.5 (1.4, 4.0) | 9.3 | (5.2, 15.3) | 4 | 0.7 (0.2, 1.8) | 2.9 | (0.8, 7.5) |
| Pyrexia | 42 | 6.9 (5.0, 9.2) | 26.0 | (18.7, 35.1) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Swelling | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Immune system disorders | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Allergic oedema | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Infections and infestations | 3 | 0.5 (0.1, 1.4) | 1.9 | (0.4, 5.4) | 5 | 0.9 (0.3, 2.0) | 3.7 | (1.2, 8.6) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Candida infection | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Cholangitis infective | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Conjunctivitis | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Helicobacter infection | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Herpes zoster | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Kidney infection | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Latent tuberculosis | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Septic shock | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Urinary tract infection | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Injury, poisoning and procedural complications | 8 | 1.3 (0.6, 2.6) | 5.0 | (2.1, 9.8) | 4 | 0.7 (0.2, 1.8) | 2.9 | (0.8, 7.5) |
| Bone contusion | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Corneal abrasion | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |

## 14.64. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: All Others

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=612, TE[b]=1.6) | | | | Placebo (N[a]=580, TE[b]=1.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Exposure during pregnancy | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Fall | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Joint injury | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Ligament sprain | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Periorbital haemorrhage | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Procedural pain | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Stoma complication | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Tendon rupture | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Investigations | 4 | 0.7 (0.2, 1.7) | 2.5 | (0.7, 6.3) | 2 | 0.3 (0.0, 1.2) | 1.5 | (0.2, 5.3) |
| Blood glucose increased | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Body temperature increased | 3 | 0.5 (0.1, 1.4) | 1.9 | (0.4, 5.4) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Inflammatory marker increased | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Metabolism and nutrition disorders | 6 | 1.0 (0.4, 2.1) | 3.7 | (1.4, 8.1) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Decreased appetite | 4 | 0.7 (0.2, 1.7) | 2.5 | (0.7, 6.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Glucose tolerance impaired | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Type 2 diabetes mellitus | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Musculoskeletal and connective tissue disorders | 56 | 9.2 (7.0, 11.7) | 34.7 | (26.2, 45.0) | 10 | 1.7 (0.8, 3.1) | 7.3 | (3.5, 13.5) |
| Arthralgia | 7 | 1.1 (0.5, 2.3) | 4.3 | (1.7, 8.9) | 4 | 0.7 (0.2, 1.8) | 2.9 | (0.8, 7.5) |
| Musculoskeletal chest pain | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Myalgia | 43 | 7.0 (5.1, 9.3) | 26.6 | (19.3, 35.9) | 5 | 0.9 (0.3, 2.0) | 3.7 | (1.2, 8.6) |
| Neck pain | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Pain in extremity | 4 | 0.7 (0.2, 1.7) | 2.5 | (0.7, 6.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Rotator cuff syndrome | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Uterine leiomyoma | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Nervous system disorders | 53 | 8.7 (6.6, 11.2) | 32.8 | (24.6, 42.9) | 7 | 1.2 (0.5, 2.5) | 5.1 | (2.1, 10.6) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Dizziness | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Headache | 48 | 7.8 (5.8, 10.3) | 29.7 | (21.9, 39.4) | 5 | 0.9 (0.3, 2.0) | 3.7 | (1.2, 8.6) |

## 14.64. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: All Others

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=612, TE[b]=1.6) | | | | Placebo (N[a]=580, TE[b]=1.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Hypoaesthesia | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Lethargy | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Migraine | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Paraesthesia | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Seizure | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Tension headache | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Tremor | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Pregnancy, puerperium and perinatal conditions | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Abortion spontaneous | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Psychiatric disorders | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 3 | 0.5 (0.1, 1.5) | 2.2 | (0.5, 6.4) |
| Adjustment disorder with mixed anxiety and depressed mood | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Attention deficit hyperactivity disorder | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Depression | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Nightmare | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Stress | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Suicidal ideation | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Reproductive system and breast disorders | 4 | 0.7 (0.2, 1.7) | 2.5 | (0.7, 6.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Adenomyosis | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Breast pain | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Endometriosis | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Heavy menstrual bleeding | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Menstruation irregular | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Ovarian cyst | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Respiratory, thoracic and mediastinal disorders | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Asthma exercise induced | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Dry throat | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Epistaxis | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Skin and subcutaneous tissue disorders | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Dermatitis allergic | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Pruritus | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Rash erythematous | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |

## 14.64. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: All Others

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=612, TE[b]=1.6) | | | | Placebo (N[a]=580, TE[b]=1.4) | | | |
| | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Surgical and medical procedures | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Abortion induced | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Vascular disorders | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Hot flush | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |

Note: MedDRA (v24.1) coding dictionary applied.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:22)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_race_6m_saf

## 14.65. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Hispanic/Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=757, TE[b]=2.0) | | | | Placebo (N[a]=749, TE[b]=1.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 282 | 37.3 (33.8, 40.8) | 140.1 | (124.2, 157.5) | 74 | 9.9 (7.8, 12.2) | 41.5 | (32.6, 52.0) |
| Blood and lymphatic system disorders | 29 | 3.8 (2.6, 5.5) | 14.4 | (9.7, 20.7) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Lymphadenopathy | 29 | 3.8 (2.6, 5.5) | 14.4 | (9.7, 20.7) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Cardiac disorders | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 2 | 0.3 (0.0, 1.0) | 1.1 | (0.1, 4.0) |
| Acute myocardial infarction | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Coronary artery insufficiency | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Ear and labyrinth disorders | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Ear pain | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Endocrine disorders | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Goitre | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Hypothyroidism | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Eye disorders | 2 | 0.3 (0.0, 1.0) | 1.0 | (0.1, 3.6) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Eye pain | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Keratitis | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Gastrointestinal disorders | 13 | 1.7 (0.9, 2.9) | 6.5 | (3.4, 11.0) | 5 | 0.7 (0.2, 1.6) | 2.8 | (0.9, 6.5) |
| Constipation | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Diarrhoea | 6 | 0.8 (0.3, 1.7) | 3.0 | (1.1, 6.5) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Dyspepsia | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Gastrooesophageal reflux disease | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Nausea | 5 | 0.7 (0.2, 1.5) | 2.5 | (0.8, 5.8) | 3 | 0.4 (0.1, 1.2) | 1.7 | (0.3, 4.9) |
| Paraesthesia oral | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Vomiting | 2 | 0.3 (0.0, 1.0) | 1.0 | (0.1, 3.6) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| General disorders and administration site conditions | 247 | 32.6 (29.3, 36.1) | 122.7 | (107.9, 139.0) | 39 | 5.2 (3.7, 7.0) | 21.8 | (15.5, 29.9) |
| Asthenia | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Axillary pain | 2 | 0.3 (0.0, 1.0) | 1.0 | (0.1, 3.6) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Chest discomfort | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Chest pain | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Chills | 55 | 7.3 (5.5, 9.4) | 27.3 | (20.6, 35.6) | 4 | 0.5 (0.1, 1.4) | 2.2 | (0.6, 5.7) |
| Fatigue | 52 | 6.9 (5.2, 8.9) | 25.8 | (19.3, 33.9) | 14 | 1.9 (1.0, 3.1) | 7.8 | (4.3, 13.2) |

## 14.65. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Hispanic/Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=757, TE[b]=2.0) | | | | Placebo (N[a]=749, TE[b]=1.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Injection site discomfort | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Injection site erythema | 3 | 0.4 (0.1, 1.2) | 1.5 | (0.3, 4.4) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Injection site oedema | 3 | 0.4 (0.1, 1.2) | 1.5 | (0.3, 4.4) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Injection site pain | 160 | 21.1 (18.3, 24.2) | 79.5 | (67.7, 92.8) | 21 | 2.8 (1.7, 4.3) | 11.8 | (7.3, 18.0) |
| Injection site paraesthesia | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Injection site swelling | 2 | 0.3 (0.0, 1.0) | 1.0 | (0.1, 3.6) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Malaise | 12 | 1.6 (0.8, 2.8) | 6.0 | (3.1, 10.4) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Pain | 31 | 4.1 (2.8, 5.8) | 15.4 | (10.5, 21.9) | 5 | 0.7 (0.2, 1.6) | 2.8 | (0.9, 6.5) |
| Peripheral swelling | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Pyrexia | 41 | 5.4 (3.9, 7.3) | 20.4 | (14.6, 27.6) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Sluggishness | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Swelling | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Vaccination site pain | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Hepatobiliary disorders | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Bile duct stone | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Immune system disorders | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 2 | 0.3 (0.0, 1.0) | 1.1 | (0.1, 4.0) |
| Allergic oedema | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Food allergy | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Seasonal allergy | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Infections and infestations | 3 | 0.4 (0.1, 1.2) | 1.5 | (0.3, 4.4) | 4 | 0.5 (0.1, 1.4) | 2.2 | (0.6, 5.7) |
| Cellulitis | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Hordeolum | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Infected dermal cyst | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Otitis externa | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Pneumonia | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Rhinitis | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Sinusitis | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Injury, poisoning and procedural complications | 3 | 0.4 (0.1, 1.2) | 1.5 | (0.3, 4.4) | 6 | 0.8 (0.3, 1.7) | 3.4 | (1.2, 7.3) |
| Animal bite | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Contusion | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Fall | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Joint injury | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Ligament sprain | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 2 | 0.3 (0.0, 1.0) | 1.1 | (0.1, 4.0) |

## 14.65. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Hispanic/Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=757, TE[b]=2.0) | | | | Placebo (N[a]=749, TE[b]=1.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Meniscus injury | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Periorbital haemorrhage | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Skin laceration | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Wrist fracture | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Investigations | 17 | 2.2 (1.3, 3.6) | 8.4 | (4.9, 13.5) | 3 | 0.4 (0.1, 1.2) | 1.7 | (0.3, 4.9) |
| Body temperature increased | 17 | 2.2 (1.3, 3.6) | 8.4 | (4.9, 13.5) | 2 | 0.3 (0.0, 1.0) | 1.1 | (0.1, 4.0) |
| Heart rate increased | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Musculoskeletal and connective tissue disorders | 67 | 8.9 (6.9, 11.1) | 33.3 | (25.8, 42.3) | 9 | 1.2 (0.6, 2.3) | 5.0 | (2.3, 9.6) |
| Arthralgia | 5 | 0.7 (0.2, 1.5) | 2.5 | (0.8, 5.8) | 3 | 0.4 (0.1, 1.2) | 1.7 | (0.3, 4.9) |
| Myalgia | 55 | 7.3 (5.5, 9.4) | 27.3 | (20.6, 35.6) | 5 | 0.7 (0.2, 1.6) | 2.8 | (0.9, 6.5) |
| Neck pain | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Osteoarthritis | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Pain in extremity | 5 | 0.7 (0.2, 1.5) | 2.5 | (0.8, 5.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Rotator cuff syndrome | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Synovial cyst | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Trigger finger | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Nervous system disorders | 55 | 7.3 (5.5, 9.4) | 27.3 | (20.6, 35.6) | 14 | 1.9 (1.0, 3.1) | 7.8 | (4.3, 13.2) |
| Bell's palsy | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Cervicobrachial syndrome | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Dizziness | 2 | 0.3 (0.0, 1.0) | 1.0 | (0.1, 3.6) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Headache | 51 | 6.7 (5.1, 8.8) | 25.3 | (18.9, 33.3) | 11 | 1.5 (0.7, 2.6) | 6.2 | (3.1, 11.0) |
| Hypoaesthesia | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Lethargy | 2 | 0.3 (0.0, 1.0) | 1.0 | (0.1, 3.6) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Somnolence | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Psychiatric disorders | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 4 | 0.5 (0.1, 1.4) | 2.2 | (0.6, 5.7) |
| Anxiety | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 2 | 0.3 (0.0, 1.0) | 1.1 | (0.1, 4.0) |
| Attention deficit hyperactivity disorder | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Nightmare | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Renal and urinary disorders | 3 | 0.4 (0.1, 1.2) | 1.5 | (0.3, 4.4) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Nephrolithiasis | 2 | 0.3 (0.0, 1.0) | 1.0 | (0.1, 3.6) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |

## 14.65. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Hispanic/Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=757, TE[b]=2.0) | | | | Placebo (N[a]=749, TE[b]=1.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Renal colic | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Reproductive system and breast disorders | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Heavy menstrual bleeding | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Respiratory, thoracic and mediastinal disorders | 5 | 0.7 (0.2, 1.5) | 2.5 | (0.8, 5.8) | 6 | 0.8 (0.3, 1.7) | 3.4 | (1.2, 7.3) |
| Asthma | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Dyspnoea | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Nasal congestion | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Pharyngeal swelling | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Pulmonary congestion | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Rhinorrhoea | 3 | 0.4 (0.1, 1.2) | 1.5 | (0.3, 4.4) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Sinus congestion | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Sleep apnoea syndrome | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Sneezing | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 2 | 0.3 (0.0, 1.0) | 1.1 | (0.1, 4.0) |
| Skin and subcutaneous tissue disorders | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 2 | 0.3 (0.0, 1.0) | 1.1 | (0.1, 4.0) |
| Cold sweat | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Dermatitis allergic | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Night sweats | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Vascular disorders | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 3 | 0.4 (0.1, 1.2) | 1.7 | (0.3, 4.9) |
| Deep vein thrombosis | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Flushing | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Hypertension | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |

## 14.65. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Hispanic/Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=757, TE[b]=2.0) | | | | Placebo (N[a]=749, TE[b]=1.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:26)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ethnic_6m_saf

## 14.66. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 1050 | 24.5 (23.2, 25.8) | 95.4 | (89.7, 101.3) | 320 | 7.5 (6.7, 8.3) | 33.7 | (30.1, 37.6) |
| Blood and lymphatic system disorders | 113 | 2.6 (2.2, 3.2) | 10.3 | (8.5, 12.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Anaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Iron deficiency anaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lymph node pain | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lymphadenitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lymphadenopathy | 106 | 2.5 (2.0, 3.0) | 9.6 | (7.9, 11.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Lymphocytosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lymphopenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Neutropenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Thrombocytopenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cardiac disorders | 13 | 0.3 (0.2, 0.5) | 1.2 | (0.6, 2.0) | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) |
| Acute myocardial infarction | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Atrial fibrillation | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Atrial flutter | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Cardiac failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Palpitations | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pericarditis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Supraventricular tachycardia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Tachycardia | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Congenital, familial and genetic disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Thalassaemia beta | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ear and labyrinth disorders | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Ear pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Tinnitus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Vertigo | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vertigo positional | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Endocrine disorders | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.1) |

## 14.66. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Goitre | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hypothyroidism | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Thyroid cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Thyroid mass | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Eye disorders | 9 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Cataract | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Chalazion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Diplopia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dry age-related macular degeneration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dry eye | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Eyelid ptosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Glaucoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Macular degeneration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ocular hyperaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Photophobia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vitreous detachment | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Gastrointestinal disorders | 79 | 1.8 (1.5, 2.3) | 7.2 | (5.7, 8.9) | 42 | 1.0 (0.7, 1.3) | 4.4 | (3.2, 6.0) |
| Abdominal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Abdominal pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Abdominal pain upper | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.1) |
| Aphthous ulcer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ascites | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Constipation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dental caries | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dental cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Diarrhoea | 20 | 0.5 (0.3, 0.7) | 1.8 | (1.1, 2.8) | 12 | 0.3 (0.1, 0.5) | 1.3 | (0.7, 2.2) |
| Diverticulum | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dry mouth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dyspepsia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Gastric fistula | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Gastrooesophageal reflux disease | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) |
| Gingival pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Haemorrhoids | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hypoaesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hypoaesthesia teeth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Inguinal hernia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nausea | 46 | 1.1 (0.8, 1.4) | 4.2 | (3.1, 5.6) | 14 | 0.3 (0.2, 0.6) | 1.5 | (0.8, 2.5) |

## 14.66. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Oesophageal ulcer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Parotid duct obstruction | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Toothache | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Vomiting | 10 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| General disorders and administration site conditions | 833 | 19.4 (18.3, 20.7) | 75.7 | (70.6, 81.0) | 124 | 2.9 (2.4, 3.5) | 13.1 | (10.9, 15.6) |
| Asthenia | 7 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Axillary pain | 11 | 0.3 (0.1, 0.5) | 1.0 | (0.5, 1.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Chest discomfort | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Chest pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Chills | 181 | 4.2 (3.6, 4.9) | 16.4 | (14.1, 19.0) | 7 | 0.2 (0.1, 0.3) | 0.7 | (0.3, 1.5) |
| Cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Drug withdrawal syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Fatigue | 321 | 7.5 (6.7, 8.3) | 29.2 | (26.1, 32.5) | 50 | 1.2 (0.9, 1.5) | 5.3 | (3.9, 6.9) |
| Feeling abnormal | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Feeling hot | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Granuloma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Injection site bruising | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Injection site erythema | 19 | 0.4 (0.3, 0.7) | 1.7 | (1.0, 2.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site hypoaesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site induration | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site inflammation | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site irritation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site lymphadenopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Injection site pain | 495 | 11.5 (10.6, 12.5) | 45.0 | (41.1, 49.1) | 59 | 1.4 (1.1, 1.8) | 6.2 | (4.7, 8.0) |
| Injection site pruritus | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site reaction | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site swelling | 19 | 0.4 (0.3, 0.7) | 1.7 | (1.0, 2.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Injection site vesicles | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |

## 14.66. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Injection site warmth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Injury associated with device | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Malaise | 23 | 0.5 (0.3, 0.8) | 2.1 | (1.3, 3.1) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Metaplasia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pain | 106 | 2.5 (2.0, 3.0) | 9.6 | (7.9, 11.6) | 12 | 0.3 (0.1, 0.5) | 1.3 | (0.7, 2.2) |
| Peripheral swelling | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Pyrexia | 209 | 4.9 (4.3, 5.6) | 19.0 | (16.5, 21.7) | 7 | 0.2 (0.1, 0.3) | 0.7 | (0.3, 1.5) |
| Swelling | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vaccination site pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vaccination site rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hepatobiliary disorders | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Cholelithiasis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hepatic cirrhosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hepatic steatosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Immune system disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Allergy to arthropod sting | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Infections and infestations | 33 | 0.8 (0.5, 1.1) | 3.0 | (2.1, 4.2) | 39 | 0.9 (0.7, 1.2) | 4.1 | (2.9, 5.6) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Abscess | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Acute sinusitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Adenoiditis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Appendicitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Appendicitis perforated | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Arthritis infective | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Candida infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Cellulitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Conjunctivitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Conjunctivitis bacterial | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cystitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |

## 14.66. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Device related infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Diverticulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ear infection | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Empyema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Epididymitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Eye infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Groin abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hand-foot-and-mouth disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Helicobacter infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Herpes zoster | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Hordeolum | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Kidney infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Latent tuberculosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Mastitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Onychomycosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Oral herpes | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Otitis externa | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Otitis media | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Otitis media acute | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Peritonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Salmonellosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Sepsis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Septic shock | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Sinusitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tooth abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tooth infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Urinary tract infection | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 9 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.8) |
| Varicella zoster virus infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vestibular neuronitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vulvovaginal mycotic infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Injury, poisoning and procedural complications | 21 | 0.5 (0.3, 0.7) | 1.9 | (1.2, 2.9) | 30 | 0.7 (0.5, 1.0) | 3.2 | (2.1, 4.5) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ankle fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |

## 14.66. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Arthropod sting | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Bone contusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Burns third degree | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cartilage injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Concussion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Contusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Corneal abrasion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Craniocerebral injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Exposure during pregnancy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Fall | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 9 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.8) |
| Head injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hip fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Humerus fracture | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Joint injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ligament rupture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ligament sprain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Limb crushing injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Limb injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Meniscus injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Muscle strain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Musculoskeletal injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Neck injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Post procedural haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Procedural pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Road traffic accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Skin abrasion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Skin laceration | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Stoma complication | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Stress fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tendon rupture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tibia fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tooth fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Investigations | 18 | 0.4 (0.2, 0.7) | 1.6 | (1.0, 2.6) | 10 | 0.2 (0.1, 0.4) | 1.1 | (0.5, 1.9) |

## 14.66. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Alpha 1 foetoprotein increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Antinuclear antibody positive | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Blood cholesterol increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Blood creatinine increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Blood glucose increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Blood pressure increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Body temperature increased | 13 | 0.3 (0.2, 0.5) | 1.2 | (0.6, 2.0) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hepatic enzyme increased | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Inflammatory marker increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lipase increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Prostatic specific antigen increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Respiratory rate increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Metabolism and nutrition disorders | 20 | 0.5 (0.3, 0.7) | 1.8 | (1.1, 2.8) | 12 | 0.3 (0.1, 0.5) | 1.3 | (0.7, 2.2) |
| Decreased appetite | 9 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dehydration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Diabetes mellitus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Diabetic ketoacidosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Glucose tolerance impaired | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Gout | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.1) |
| Hypercholesterolaemia | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hypokalaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hyponatraemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Iron deficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Type 2 diabetes mellitus | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Vitamin D deficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Musculoskeletal and connective tissue disorders | 288 | 6.7 (6.0, 7.5) | 26.2 | (23.2, 29.4) | 46 | 1.1 (0.8, 1.4) | 4.8 | (3.5, 6.5) |

## 14.66. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Arthralgia | 37 | 0.9 (0.6, 1.2) | 3.4 | (2.4, 4.6) | 13 | 0.3 (0.2, 0.5) | 1.4 | (0.7, 2.3) |
| Arthritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Back pain | 8 | 0.2 (0.1, 0.4) | 0.7 | (0.3, 1.4) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.1) |
| Bone cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Bone pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Foot deformity | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Groin pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Joint effusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Joint stiffness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Joint swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Metatarsalgia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Muscle fatigue | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Muscle swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Muscular weakness | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Musculoskeletal chest pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Musculoskeletal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Musculoskeletal pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Musculoskeletal stiffness | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Myalgia | 186 | 4.3 (3.7, 5.0) | 16.9 | (14.6, 19.5) | 15 | 0.4 (0.2, 0.6) | 1.6 | (0.9, 2.6) |
| Neck pain | 10 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Osteoporosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pain in extremity | 52 | 1.2 (0.9, 1.6) | 4.7 | (3.5, 6.2) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Pain in jaw | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Plantar fasciitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Psoriatic arthropathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Rotator cuff syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Scoliosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Spinal stenosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Synovial cyst | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Tendonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.66. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 15 | 0.3 (0.2, 0.6) | 1.4 | (0.8, 2.2) | 11 | 0.3 (0.1, 0.5) | 1.2 | (0.6, 2.1) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Basal cell carcinoma | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Benign neoplasm of thyroid gland | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Breast cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Focal nodular hyperplasia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Granular cell tumour | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Malignant melanoma | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Melanocytic naevus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Prostate cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Skin cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Squamous cell carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Squamous cell carcinoma of skin | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Uterine leiomyoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nervous system disorders | 241 | 5.6 (5.0, 6.4) | 21.9 | (19.2, 24.8) | 55 | 1.3 (1.0, 1.7) | 5.8 | (4.4, 7.5) |
| Altered state of consciousness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Carpal tunnel syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.66. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Cervical radiculopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dizziness | 7 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Dysgeusia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Headache | 208 | 4.9 (4.2, 5.5) | 18.9 | (16.4, 21.6) | 40 | 0.9 (0.7, 1.3) | 4.2 | (3.0, 5.7) |
| Hyperaesthesia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hypoaesthesia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hypotonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Lethargy | 10 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Migraine | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Migraine with aura | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nerve compression | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Neuralgic amyotrophy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Paraesthesia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Parosmia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Sciatica | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Seizure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Syncope | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Taste disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Tension headache | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tremor | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pregnancy, puerperium and perinatal conditions | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Abortion spontaneous | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pregnancy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Psychiatric disorders | 16 | 0.4 (0.2, 0.6) | 1.5 | (0.8, 2.4) | 11 | 0.3 (0.1, 0.5) | 1.2 | (0.6, 2.1) |
| Abnormal dreams | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Adjustment disorder with mixed anxiety and depressed mood | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Alcoholism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Anxiety | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Attention deficit hyperactivity disorder | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Depression | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |

## 14.66. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Generalised anxiety disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Insomnia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Mood altered | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Poor quality sleep | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Stress | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Renal and urinary disorders | 8 | 0.2 (0.1, 0.4) | 0.7 | (0.3, 1.4) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Cystitis haemorrhagic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dysuria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Haematuria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Renal cyst | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Stress urinary incontinence | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Urinary incontinence | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Reproductive system and breast disorders | 9 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.6) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.1) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Atrophic vulvovaginitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Breast calcifications | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Breast pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Endometriosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intermenstrual bleeding | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Menstruation irregular | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ovarian cyst | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Prostatitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Scrotal disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Respiratory, thoracic and mediastinal disorders | 10 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.7) | 11 | 0.3 (0.1, 0.5) | 1.2 | (0.6, 2.1) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Asthma | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Asthma exercise induced | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dry throat | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |

## 14.66. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Epistaxis | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nasal congestion | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Nasal polyps | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pleural effusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pleurisy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Respiratory failure | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Sinus congestion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Throat tightness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Skin and subcutaneous tissue disorders | 24 | 0.6 (0.4, 0.8) | 2.2 | (1.4, 3.2) | 10 | 0.2 (0.1, 0.4) | 1.1 | (0.5, 1.9) |
| Alopecia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Alopecia areata | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dermal cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Dermatitis contact | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dry skin | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Erythema | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hyperhidrosis | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.1) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intertrigo | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Night sweats | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pruritus | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Psoriasis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Rash | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Rash erythematous | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Rash papular | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Urticaria | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Xanthoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Surgical and medical procedures | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Abortion induced | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Bunion operation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Gastrectomy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vascular disorders | 7 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.3) | 9 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.8) |
| Flushing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Haematoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hot flush | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Hypertension | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Hypotension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.66. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Peripheral venous disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:31) Source Data: adae Table Generation: 31MAR2022 (14:26)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ethnic_6m_saf

## 14.67. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Not Reported

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=12, TE[b]=0.0) | | | | Placebo (N[a]=8, TE[b]=0.0) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 3 | 25.0 (5.5, 57.2) | 121.8 | (25.1, 355.8) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| General disorders and administration site conditions | 3 | 25.0 (5.5, 57.2) | 121.8 | (25.1, 355.8) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Chills | 1 | 8.3 (0.2, 38.5) | 40.6 | (1.0, 226.1) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Injection site pain | 2 | 16.7 (2.1, 48.4) | 81.2 | (9.8, 293.2) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Pyrexia | 1 | 8.3 (0.2, 38.5) | 40.6 | (1.0, 226.1) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Nervous system disorders | 1 | 8.3 (0.2, 38.5) | 40.6 | (1.0, 226.1) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |
| Headache | 1 | 8.3 (0.2, 38.5) | 40.6 | (1.0, 226.1) | 0 | 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:26)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ethnic_6m_saf

## 14.68. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: Brazil

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=580, TE[b]=1.6) | | | | Placebo (N[a]=582, TE[b]=1.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 414 | 71.4 (67.5, 75.0) | 256.1 | (232.0, 282.0) | 92 | 15.8 (12.9, 19.0) | 57.3 | (46.2, 70.3) |
| Blood and lymphatic system disorders | 46 | 7.9 (5.9, 10.4) | 28.5 | (20.8, 38.0) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Lymphadenopathy | 46 | 7.9 (5.9, 10.4) | 28.5 | (20.8, 38.0) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Lymphopenia | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Neutropenia | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Thrombocytopenia | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Cardiac disorders | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.2, 4.5) |
| Coronary artery insufficiency | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Palpitations | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Endocrine disorders | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Goitre | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Hypothyroidism | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Eye disorders | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Eye pain | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Gastrointestinal disorders | 13 | 2.2 (1.2, 3.8) | 8.0 | (4.3, 13.7) | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.2, 4.5) |
| Diarrhoea | 5 | 0.9 (0.3, 2.0) | 3.1 | (1.0, 7.2) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Gastric fistula | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Nausea | 4 | 0.7 (0.2, 1.8) | 2.5 | (0.7, 6.3) | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.2, 4.5) |
| Vomiting | 4 | 0.7 (0.2, 1.8) | 2.5 | (0.7, 6.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| General disorders and administration site conditions | 381 | 65.7 (61.7, 69.6) | 235.7 | (212.6, 260.5) | 61 | 10.5 (8.1, 13.3) | 38.0 | (29.1, 48.8) |
| Asthenia | 4 | 0.7 (0.2, 1.8) | 2.5 | (0.7, 6.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Chills | 82 | 14.1 (11.4, 17.2) | 50.7 | (40.3, 63.0) | 3 | 0.5 (0.1, 1.5) | 1.9 | (0.4, 5.5) |
| Fatigue | 95 | 16.4 (13.5, 19.6) | 58.8 | (47.5, 71.8) | 18 | 3.1 (1.8, 4.8) | 11.2 | (6.6, 17.7) |
| Feeling hot | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Granuloma | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Injection site discomfort | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Injection site erythema | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Injection site oedema | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Injection site pain | 280 | 48.3 (44.1, 52.4) | 173.2 | (153.5, 194.7) | 40 | 6.9 (5.0, 9.2) | 24.9 | (17.8, 33.9) |
| Injection site paraesthesia | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |

## 14.68. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: Brazil

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=580, TE[b]=1.6) | | | | Placebo (N[a]=582, TE[b]=1.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Injection site swelling | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Malaise | 10 | 1.7 (0.8, 3.1) | 6.2 | (3.0, 11.4) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Pain | 20 | 3.4 (2.1, 5.3) | 12.4 | (7.6, 19.1) | 6 | 1.0 (0.4, 2.2) | 3.7 | (1.4, 8.1) |
| Pyrexia | 65 | 11.2 (8.8, 14.1) | 40.2 | (31.0, 51.2) | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.2, 4.5) |
| Hepatobiliary disorders | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Bile duct stone | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Infections and infestations | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 4 | 0.7 (0.2, 1.8) | 2.5 | (0.7, 6.4) |
| Abdominal sepsis | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Hordeolum | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Rhinitis | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Urinary tract infection | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.2, 4.5) |
| Injury, poisoning and procedural complications | 3 | 0.5 (0.1, 1.5) | 1.9 | (0.4, 5.4) | 4 | 0.7 (0.2, 1.8) | 2.5 | (0.7, 6.4) |
| Exposure during pregnancy | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Fall | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Head injury | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Ligament rupture | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Ligament sprain | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.2, 4.5) |
| Periorbital haemorrhage | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Investigations | 15 | 2.6 (1.5, 4.2) | 9.3 | (5.2, 15.3) | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.2, 4.5) |
| Body temperature increased | 15 | 2.6 (1.5, 4.2) | 9.3 | (5.2, 15.3) | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.2, 4.5) |
| Metabolism and nutrition disorders | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Decreased appetite | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Musculoskeletal and connective tissue disorders | 98 | 16.9 (13.9, 20.2) | 60.6 | (49.2, 73.9) | 8 | 1.4 (0.6, 2.7) | 5.0 | (2.2, 9.8) |
| Arthralgia | 10 | 1.7 (0.8, 3.1) | 6.2 | (3.0, 11.4) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Musculoskeletal pain | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Myalgia | 85 | 14.7 (11.9, 17.8) | 52.6 | (42.0, 65.0) | 6 | 1.0 (0.4, 2.2) | 3.7 | (1.4, 8.1) |

## 14.68. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: Brazil

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=580, TE[b]=1.6) | | | | Placebo (N[a]=582, TE[b]=1.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Neck pain | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Pain in extremity | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Synovial cyst | 4 | 0.7 (0.2, 1.8) | 2.5 | (0.7, 6.3) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Uterine leiomyoma | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Nervous system disorders | 74 | 12.8 (10.2, 15.8) | 45.8 | (35.9, 57.5) | 21 | 3.6 (2.2, 5.5) | 13.1 | (8.1, 20.0) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Cervicobrachial syndrome | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Dizziness | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Headache | 72 | 12.4 (9.8, 15.4) | 44.5 | (34.8, 56.1) | 18 | 3.1 (1.8, 4.8) | 11.2 | (6.6, 17.7) |
| Paraesthesia | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Somnolence | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Pregnancy, puerperium and perinatal conditions | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Abortion spontaneous | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Psychiatric disorders | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.2, 4.5) |
| Anxiety | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Depression | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Renal and urinary disorders | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Renal colic | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Reproductive system and breast disorders | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Menstruation irregular | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Prostatitis | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Respiratory, thoracic and mediastinal disorders | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Rhinorrhoea | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Skin and subcutaneous tissue disorders | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Night sweats | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Rash erythematous | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |

## 14.68. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: Brazil

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=580, TE[b]=1.6) | | | | Placebo (N[a]=582, TE[b]=1.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Surgical and medical procedures | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Abortion induced | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Vascular disorders | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Hypertension | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:31)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_cntry_6m_saf

## 14.69. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: South Africa

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=123, TE[b]=0.4) | | | | Placebo (N[a]=128, TE[b]=0.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 8 | 6.5 (2.8, 12.4) | 19.7 | (8.5, 38.7) | 2 | 1.6 (0.2, 5.5) | 5.8 | (0.7, 21.0) |
| Blood and lymphatic system disorders | 5 | 4.1 (1.3, 9.2) | 12.3 | (4.0, 28.7) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Lymphadenopathy | 5 | 4.1 (1.3, 9.2) | 12.3 | (4.0, 28.7) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Gastrointestinal disorders | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 1 | 0.8 (0.0, 4.3) | 2.9 | (0.1, 16.2) |
| Diarrhoea | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 1 | 0.8 (0.0, 4.3) | 2.9 | (0.1, 16.2) |
| General disorders and administration site conditions | 3 | 2.4 (0.5, 7.0) | 7.4 | (1.5, 21.5) | 1 | 0.8 (0.0, 4.3) | 2.9 | (0.1, 16.2) |
| Chills | 1 | 0.8 (0.0, 4.4) | 2.5 | (0.1, 13.7) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Fatigue | 1 | 0.8 (0.0, 4.4) | 2.5 | (0.1, 13.7) | 1 | 0.8 (0.0, 4.3) | 2.9 | (0.1, 16.2) |
| Injection site pain | 1 | 0.8 (0.0, 4.4) | 2.5 | (0.1, 13.7) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Pyrexia | 1 | 0.8 (0.0, 4.4) | 2.5 | (0.1, 13.7) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Musculoskeletal and connective tissue disorders | 1 | 0.8 (0.0, 4.4) | 2.5 | (0.1, 13.7) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Myalgia | 1 | 0.8 (0.0, 4.4) | 2.5 | (0.1, 13.7) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Nervous system disorders | 1 | 0.8 (0.0, 4.4) | 2.5 | (0.1, 13.7) | 2 | 1.6 (0.2, 5.5) | 5.8 | (0.7, 21.0) |
| Headache | 1 | 0.8 (0.0, 4.4) | 2.5 | (0.1, 13.7) | 2 | 1.6 (0.2, 5.5) | 5.8 | (0.7, 21.0) |
| Psychiatric disorders | 1 | 0.8 (0.0, 4.4) | 2.5 | (0.1, 13.7) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |
| Anxiety | 1 | 0.8 (0.0, 4.4) | 2.5 | (0.1, 13.7) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence Rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:31)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: /lida2_ubBIA/C4591031_A_SBLA/adae_s131_cntry_6m_saf

## 14.70. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 913 | 21.0 (19.8, 22.2) | 82.8 | (77.6, 88.4) | 300 | 7.0 (6.2, 7.8) | 32.1 | (28.6, 36.0) |
| Blood and lymphatic system disorders | 91 | 2.1 (1.7, 2.6) | 8.3 | (6.6, 10.1) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.1) |
| Anaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Iron deficiency anaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lymph node pain | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lymphadenitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lymphadenopathy | 84 | 1.9 (1.5, 2.4) | 7.6 | (6.1, 9.4) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.1) |
| Lymphocytosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cardiac disorders | 12 | 0.3 (0.1, 0.5) | 1.1 | (0.6, 1.9) | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) |
| Acute myocardial infarction | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Atrial fibrillation | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Atrial flutter | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Cardiac failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Palpitations | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pericarditis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Supraventricular tachycardia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Tachycardia | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Congenital, familial and genetic disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Thalassaemia beta | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ear and labyrinth disorders | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Ear pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Tinnitus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Vertigo | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vertigo positional | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Endocrine disorders | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.1) |
| Goitre | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hypothyroidism | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Thyroid cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Thyroid mass | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |

## 14.70. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Eye disorders | 10 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Cataract | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Chalazion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Diplopia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dry age-related macular degeneration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dry eye | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Eyelid ptosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Glaucoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Keratitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Macular degeneration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ocular hyperaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Photophobia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vitreous detachment | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Gastrointestinal disorders | 79 | 1.8 (1.4, 2.3) | 7.2 | (5.7, 8.9) | 44 | 1.0 (0.7, 1.4) | 4.7 | (3.4, 6.3) |
| Abdominal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Abdominal pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Abdominal pain upper | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.1) |
| Aphthous ulcer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ascites | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Constipation | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dental caries | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dental cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Diarrhoea | 21 | 0.5 (0.3, 0.7) | 1.9 | (1.2, 2.9) | 12 | 0.3 (0.1, 0.5) | 1.3 | (0.7, 2.2) |
| Diverticulum | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dry mouth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dyspepsia | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Gastrooesophageal reflux disease | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) |
| Gingival pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Haemorrhoids | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hypoaesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hypoaesthesia teeth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Inguinal hernia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nausea | 47 | 1.1 (0.8, 1.4) | 4.3 | (3.1, 5.7) | 15 | 0.3 (0.2, 0.6) | 1.6 | (0.9, 2.6) |
| Oesophageal ulcer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Paraesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Parotid duct obstruction | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.70. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Toothache | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Vomiting | 8 | 0.2 (0.1, 0.4) | 0.7 | (0.3, 1.4) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| General disorders and administration site conditions | 699 | 16.1 (15.0, 17.2) | 63.4 | (58.8, 68.3) | 101 | 2.3 (1.9, 2.8) | 10.8 | (8.8, 13.1) |
| Asthenia | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Axillary pain | 13 | 0.3 (0.2, 0.5) | 1.2 | (0.6, 2.0) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Chest discomfort | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Chest pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Chills | 154 | 3.5 (3.0, 4.1) | 14.0 | (11.9, 16.4) | 8 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.7) |
| Cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Drug withdrawal syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Fatigue | 277 | 6.4 (5.7, 7.1) | 25.1 | (22.3, 28.3) | 45 | 1.0 (0.8, 1.4) | 4.8 | (3.5, 6.4) |
| Feeling abnormal | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Feeling hot | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site bruising | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Injection site erythema | 21 | 0.5 (0.3, 0.7) | 1.9 | (1.2, 2.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site hypoaesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site induration | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site inflammation | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site irritation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site lymphadenopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Injection site oedema | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site pain | 376 | 8.6 (7.8, 9.5) | 34.1 | (30.8, 37.7) | 40 | 0.9 (0.7, 1.3) | 4.3 | (3.1, 5.8) |
| Injection site pruritus | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site reaction | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site swelling | 19 | 0.4 (0.3, 0.7) | 1.7 | (1.0, 2.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Injection site vesicles | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Injection site warmth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Injury associated with device | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |

## 14.70. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Malaise | 25 | 0.6 (0.4, 0.8) | 2.3 | (1.5, 3.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Metaplasia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pain | 117 | 2.7 (2.2, 3.2) | 10.6 | (8.8, 12.7) | 11 | 0.3 (0.1, 0.5) | 1.2 | (0.6, 2.1) |
| Peripheral swelling | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Pyrexia | 185 | 4.3 (3.7, 4.9) | 16.8 | (14.5, 19.4) | 6 | 0.1 (0.1, 0.3) | 0.6 | (0.2, 1.4) |
| Sluggishness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Swelling | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vaccination site pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vaccination site rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hepatobiliary disorders | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Cholelithiasis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hepatic cirrhosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hepatic steatosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Immune system disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Allergic oedema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Allergy to arthropod sting | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Food allergy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Seasonal allergy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Infections and infestations | 34 | 0.8 (0.5, 1.1) | 3.1 | (2.1, 4.3) | 39 | 0.9 (0.6, 1.2) | 4.2 | (3.0, 5.7) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Abscess | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Acute sinusitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Adenoiditis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Appendicitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Appendicitis perforated | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Arthritis infective | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Candida infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Cellulitis | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Conjunctivitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Conjunctivitis bacterial | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cystitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Device related infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Diverticulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ear infection | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Empyema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.70. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Epididymitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Eye infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Groin abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hand-foot-and-mouth disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Helicobacter infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Herpes zoster | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Hordeolum | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Infected dermal cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Kidney infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Latent tuberculosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Mastitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Onychomycosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Oral herpes | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Otitis externa | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Otitis media | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Otitis media acute | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Peritonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Salmonellosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Sepsis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Septic shock | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Sinusitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Tooth abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tooth infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Urinary tract infection | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 7 | 0.2 (0.1, 0.3) | 0.7 | (0.3, 1.5) |
| Varicella zoster virus infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vestibular neuronitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vulvovaginal mycotic infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Injury, poisoning and procedural complications | 21 | 0.5 (0.3, 0.7) | 1.9 | (1.2, 2.9) | 32 | 0.7 (0.5, 1.0) | 3.4 | (2.3, 4.8) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Animal bite | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ankle fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Arthropod sting | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Bone contusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Burns third degree | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |

## 14.70. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Cartilage injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Concussion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Contusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Corneal abrasion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Craniocerebral injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Fall | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 9 | 0.2 (0.1, 0.4) | 1.0 | (0.4, 1.8) |
| Hip fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Humerus fracture | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Joint injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ligament sprain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Limb crushing injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Limb injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Meniscus injury | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Muscle strain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Musculoskeletal injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Neck injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Post procedural haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Procedural pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Road traffic accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Skin abrasion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Skin laceration | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Stoma complication | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Stress fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tendon rupture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tibia fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tooth fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Wrist fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Investigations | 20 | 0.5 (0.3, 0.7) | 1.8 | (1.1, 2.8) | 11 | 0.3 (0.1, 0.5) | 1.2 | (0.6, 2.1) |
| Alpha 1 foetoprotein increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Antinuclear antibody positive | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Blood cholesterol increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Blood creatinine increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.70. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Blood glucose increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Blood pressure increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Body temperature increased | 15 | 0.3 (0.2, 0.6) | 1.4 | (0.8, 2.2) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Heart rate increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hepatic enzyme increased | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Inflammatory marker increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lipase increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Prostatic specific antigen increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Respiratory rate increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Metabolism and nutrition disorders | 19 | 0.4 (0.3, 0.7) | 1.7 | (1.0, 2.7) | 12 | 0.3 (0.1, 0.5) | 1.3 | (0.7, 2.2) |
| Decreased appetite | 8 | 0.2 (0.1, 0.4) | 0.7 | (0.3, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dehydration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Diabetes mellitus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Diabetic ketoacidosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Glucose tolerance impaired | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Gout | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.1) |
| Hypercholesterolaemia | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hypokalaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hyponatraemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Iron deficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Type 2 diabetes mellitus | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Vitamin D deficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Musculoskeletal and connective tissue disorders | 256 | 5.9 (5.2, 6.6) | 23.2 | (20.5, 26.3) | 47 | 1.1 (0.8, 1.4) | 5.0 | (3.7, 6.7) |
| Arthralgia | 32 | 0.7 (0.5, 1.0) | 2.9 | (2.0, 4.1) | 15 | 0.3 (0.2, 0.6) | 1.6 | (0.9, 2.6) |
| Arthritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Back pain | 8 | 0.2 (0.1, 0.4) | 0.7 | (0.3, 1.4) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.1) |
| Bone cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Bone pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Foot deformity | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Groin pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.70. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Joint effusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Joint stiffness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Joint swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Metatarsalgia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Muscle fatigue | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Muscle swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Muscular weakness | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Musculoskeletal chest pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Musculoskeletal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Musculoskeletal pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Musculoskeletal stiffness | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Myalgia | 155 | 3.6 (3.0, 4.2) | 14.1 | (11.9, 16.5) | 14 | 0.3 (0.2, 0.5) | 1.5 | (0.8, 2.5) |
| Neck pain | 9 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.6) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Osteoarthritis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Osteoporosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pain in extremity | 56 | 1.3 (1.0, 1.7) | 5.1 | (3.8, 6.6) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Pain in jaw | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Plantar fasciitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Psoriatic arthropathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Rotator cuff syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Scoliosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Spinal stenosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tendonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Trigger finger | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 14 | 0.3 (0.2, 0.5) | 1.3 | (0.7, 2.1) | 11 | 0.3 (0.1, 0.5) | 1.2 | (0.6, 2.1) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Basal cell carcinoma | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Benign neoplasm of thyroid gland | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.70. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Breast cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Focal nodular hyperplasia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Granular cell tumour | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Malignant melanoma | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Melanocytic naevus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Prostate cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Skin cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Squamous cell carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Squamous cell carcinoma of skin | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Nervous system disorders | 222 | 5.1 (4.5, 5.8) | 20.1 | (17.6, 23.0) | 46 | 1.1 (0.8, 1.4) | 4.9 | (3.6, 6.6) |
| Altered state of consciousness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Bell's palsy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Carpal tunnel syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Cervical radiculopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dizziness | 8 | 0.2 (0.1, 0.4) | 0.7 | (0.3, 1.4) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Dysgeusia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Headache | 187 | 4.3 (3.7, 4.9) | 17.0 | (14.6, 19.6) | 31 | 0.7 (0.5, 1.0) | 3.3 | (2.3, 4.7) |
| Hyperaesthesia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hypoaesthesia | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hypotonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Lethargy | 12 | 0.3 (0.1, 0.5) | 1.1 | (0.6, 1.9) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |

## 14.70. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Migraine | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Migraine with aura | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nerve compression | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Neuralgic amyotrophy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Paraesthesia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Parosmia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Sciatica | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Seizure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Syncope | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Taste disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Tension headache | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tremor | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pregnancy, puerperium and perinatal conditions | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pregnancy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Psychiatric disorders | 15 | 0.3 (0.2, 0.6) | 1.4 | (0.8, 2.2) | 13 | 0.3 (0.2, 0.5) | 1.4 | (0.7, 2.4) |
| Abnormal dreams | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Adjustment disorder with mixed anxiety and depressed mood | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Alcoholism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Anxiety | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Attention deficit hyperactivity disorder | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.1) |
| Depression | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Generalised anxiety disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Insomnia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Mood altered | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nightmare | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Poor quality sleep | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Stress | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Renal and urinary disorders | 10 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Cystitis haemorrhagic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.70. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Dysuria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Haematuria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nephrolithiasis | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Renal cyst | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Stress urinary incontinence | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Urinary incontinence | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Reproductive system and breast disorders | 9 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Atrophic vulvovaginitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Breast calcifications | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Breast pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Endometriosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Heavy menstrual bleeding | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Intermenstrual bleeding | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Menstruation irregular | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ovarian cyst | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Prostatitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Scrotal disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Respiratory, thoracic and mediastinal disorders | 13 | 0.3 (0.2, 0.5) | 1.2 | (0.6, 2.0) | 17 | 0.4 (0.2, 0.6) | 1.8 | (1.1, 2.9) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Asthma | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Asthma exercise induced | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dry throat | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Epistaxis | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nasal congestion | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Nasal polyps | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pharyngeal swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pleural effusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pleurisy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pulmonary congestion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |

## 14.70. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Respiratory failure | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Rhinorrhoea | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Sinus congestion | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Sleep apnoea syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Sneezing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Throat tightness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Skin and subcutaneous tissue disorders | 23 | 0.5 (0.3, 0.8) | 2.1 | (1.3, 3.1) | 12 | 0.3 (0.1, 0.5) | 1.3 | (0.7, 2.2) |
| Alopecia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Alopecia areata | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cold sweat | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dermal cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Dermatitis allergic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dermatitis contact | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dry skin | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Erythema | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hyperhidrosis | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.1) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intertrigo | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Night sweats | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pruritus | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Psoriasis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Rash | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Rash papular | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Urticaria | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Xanthoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Surgical and medical procedures | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Bunion operation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Gastrectomy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Vascular disorders | 7 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.3) | 11 | 0.3 (0.1, 0.5) | 1.2 | (0.6, 2.1) |
| Deep vein thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Flushing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Haematoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hot flush | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Hypertension | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Hypotension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Peripheral venous disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |

## 14.70. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:31)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_cntry_6m_saf

## 14.71. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Positive

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=283, TE[b]=0.8) | | | | Placebo (N[a]=259, TE[b]=0.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 71 | 25.1 (20.1, 30.6) | 83.8 | (65.5, 105.8) | 25 | 9.7 (6.3, 13.9) | 39.0 | (25.2, 57.6) |
| Blood and lymphatic system disorders | 5 | 1.8 (0.6, 4.1) | 5.9 | (1.9, 13.8) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Lymphadenopathy | 5 | 1.8 (0.6, 4.1) | 5.9 | (1.9, 13.8) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Cardiac disorders | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 2 | 0.8 (0.1, 2.8) | 3.1 | (0.4, 11.3) |
| Myocardial infarction | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Palpitations | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Pericarditis | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Ear and labyrinth disorders | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Vertigo | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Gastrointestinal disorders | 7 | 2.5 (1.0, 5.0) | 8.3 | (3.3, 17.0) | 2 | 0.8 (0.1, 2.8) | 3.1 | (0.4, 11.3) |
| Abdominal pain | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Diarrhoea | 6 | 2.1 (0.8, 4.6) | 7.1 | (2.6, 15.4) | 2 | 0.8 (0.1, 2.8) | 3.1 | (0.4, 11.3) |
| Nausea | 3 | 1.1 (0.2, 3.1) | 3.5 | (0.7, 10.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Vomiting | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| General disorders and administration site conditions | 58 | 20.5 (15.9, 25.7) | 68.5 | (52.0, 88.5) | 14 | 5.4 (3.0, 8.9) | 21.8 | (11.9, 36.7) |
| Chills | 10 | 3.5 (1.7, 6.4) | 11.8 | (5.7, 21.7) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Fatigue | 19 | 6.7 (4.1, 10.3) | 22.4 | (13.5, 35.0) | 3 | 1.2 (0.2, 3.3) | 4.7 | (1.0, 13.7) |
| Granuloma | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Injection site pain | 35 | 12.4 (8.8, 16.8) | 41.3 | (28.8, 57.5) | 6 | 2.3 (0.9, 5.0) | 9.4 | (3.4, 20.4) |
| Malaise | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Pain | 6 | 2.1 (0.8, 4.6) | 7.1 | (2.6, 15.4) | 2 | 0.8 (0.1, 2.8) | 3.1 | (0.4, 11.3) |
| Pyrexia | 14 | 4.9 (2.7, 8.2) | 16.5 | (9.0, 27.7) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Vaccination site pain | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Infections and infestations | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Sinusitis | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Tooth infection | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Injury, poisoning and procedural complications | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Ligament sprain | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Metabolism and nutrition disorders | 3 | 1.1 (0.2, 3.1) | 3.5 | (0.7, 10.4) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |

## 14.71. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Positive

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=283, TE[b]=0.8) | | | | Placebo (N[a]=259, TE[b]=0.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Decreased appetite | 2 | 0.7 (0.1, 2.5) | 2.4 | (0.3, 8.5) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Dehydration | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Musculoskeletal and connective tissue disorders | 11 | 3.9 (2.0, 6.8) | 13.0 | (6.5, 23.2) | 4 | 1.5 (0.4, 3.9) | 6.2 | (1.7, 16.0) |
| Arthralgia | 2 | 0.7 (0.1, 2.5) | 2.4 | (0.3, 8.5) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Musculoskeletal pain | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Myalgia | 8 | 2.8 (1.2, 5.5) | 9.4 | (4.1, 18.6) | 2 | 0.8 (0.1, 2.8) | 3.1 | (0.4, 11.3) |
| Pain in extremity | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Plantar fasciitis | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Nervous system disorders | 18 | 6.4 (3.8, 9.9) | 21.3 | (12.6, 33.6) | 6 | 2.3 (0.9, 5.0) | 9.4 | (3.4, 20.4) |
| Dizziness | 2 | 0.7 (0.1, 2.5) | 2.4 | (0.3, 8.5) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Headache | 15 | 5.3 (3.0, 8.6) | 17.7 | (9.9, 29.2) | 4 | 1.5 (0.4, 3.9) | 6.2 | (1.7, 16.0) |
| Lethargy | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Migraine | 0 | 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 | 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Seizure | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Syncope | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Throat tightness | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Surgical and medical procedures | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |
| Gastrectomy | 1 | 0.4 (0.0, 2.0) | 1.2 | (0.0, 6.6) | 0 | 0.0 (0.0, 1.4) | 0.0 | (0.0, 5.8) |

## 14.71. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Positive

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=283, TE[b]=0.8) | | | | Placebo (N[a]=259, TE[b]=0.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: MedDRA (v24.1) coding dictionary applied.
Note: Participants whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:26)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_base_6m_saf

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 1262 | 26.5 (25.2, 27.8) | 103.6 | (97.9, 109.5) | 368 | 7.7 (7.0, 8.5) | 34.6 | (31.2, 38.3) |
| Blood and lymphatic system disorders | 137 | 2.9 (2.4, 3.4) | 11.2 | (9.4, 13.3) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Anaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Iron deficiency anaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lymph node pain | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lymphadenitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lymphadenopathy | 130 | 2.7 (2.3, 3.2) | 10.7 | (8.9, 12.7) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Lymphocytosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lymphopenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Neutropenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Thrombocytopenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cardiac disorders | 12 | 0.3 (0.1, 0.4) | 1.0 | (0.5, 1.7) | 5 | 0.1 (0.0, 0.2) | 0.5 | (0.2, 1.1) |
| Acute myocardial infarction | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Atrial fibrillation | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Atrial flutter | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cardiac failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Coronary artery insufficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Palpitations | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Supraventricular tachycardia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Tachycardia | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Congenital, familial and genetic disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Thalassaemia beta | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ear and labyrinth disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Ear pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Tinnitus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Vertigo | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vertigo positional | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Endocrine disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Goitre | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hypothyroidism | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Thyroid cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Thyroid mass | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Eye disorders | 11 | 0.2 (0.1, 0.4) | 0.9 | (0.5, 1.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Cataract | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Chalazion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Diplopia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dry age-related macular degeneration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dry eye | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Eye pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Eyelid ptosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Glaucoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Keratitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Macular degeneration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ocular hyperaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Photophobia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vitreous detachment | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Gastrointestinal disorders | 85 | 1.8 (1.4, 2.2) | 7.0 | (5.6, 8.6) | 45 | 0.9 (0.7, 1.3) | 4.2 | (3.1, 5.7) |
| Abdominal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abdominal pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Abdominal pain upper | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Aphthous ulcer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ascites | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Constipation | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dental caries | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dental cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Diarrhoea | 20 | 0.4 (0.3, 0.6) | 1.6 | (1.0, 2.5) | 11 | 0.2 (0.1, 0.4) | 1.0 | (0.5, 1.9) |
| Diverticulum | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dry mouth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dyspepsia | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Gastric fistula | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Gastrooesophageal reflux disease | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 5 | 0.1 (0.0, 0.2) | 0.5 | (0.2, 1.1) |
| Gingival pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Haemorrhoids | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hypoaesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Hypoaesthesia teeth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Inguinal hernia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nausea | 48 | 1.0 (0.7, 1.3) | 3.9 | (2.9, 5.2) | 16 | 0.3 (0.2, 0.5) | 1.5 | (0.9, 2.4) |
| Oesophageal ulcer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Paraesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Parotid duct obstruction | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Toothache | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Vomiting | 11 | 0.2 (0.1, 0.4) | 0.9 | (0.5, 1.6) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| General disorders and administration site conditions | 1024 | 21.5 (20.3, 22.7) | 84.0 | (79.0, 89.4) | 149 | 3.1 (2.7, 3.7) | 14.0 | (11.9, 16.4) |
| Asthenia | 8 | 0.2 (0.1, 0.3) | 0.7 | (0.3, 1.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Axillary pain | 12 | 0.3 (0.1, 0.4) | 1.0 | (0.5, 1.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Chest discomfort | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Chest pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Chills | 227 | 4.8 (4.2, 5.4) | 18.6 | (16.3, 21.2) | 10 | 0.2 (0.1, 0.4) | 0.9 | (0.5, 1.7) |
| Cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Drug withdrawal syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Fatigue | 354 | 7.4 (6.7, 8.2) | 29.1 | (26.1, 32.2) | 61 | 1.3 (1.0, 1.6) | 5.7 | (4.4, 7.4) |
| Feeling abnormal | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Feeling hot | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site bruising | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Injection site discomfort | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site erythema | 22 | 0.5 (0.3, 0.7) | 1.8 | (1.1, 2.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site hypoaesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site induration | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site inflammation | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site irritation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site lymphadenopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Injection site oedema | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site pain | 621 | 13.0 (12.1, 14.0) | 51.0 | (47.0, 55.1) | 74 | 1.6 (1.2, 2.0) | 7.0 | (5.5, 8.7) |
| Injection site paraesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site pruritus | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site reaction | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site swelling | 21 | 0.4 (0.3, 0.7) | 1.7 | (1.1, 2.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injection site vesicles | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site warmth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injury associated with device | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Malaise | 34 | 0.7 (0.5, 1.0) | 2.8 | (1.9, 3.9) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Metaplasia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pain | 131 | 2.7 (2.3, 3.3) | 10.8 | (9.0, 12.8) | 15 | 0.3 (0.2, 0.5) | 1.4 | (0.8, 2.3) |
| Peripheral swelling | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Pyrexia | 237 | 5.0 (4.4, 5.6) | 19.5 | (17.1, 22.1) | 7 | 0.1 (0.1, 0.3) | 0.7 | (0.3, 1.4) |
| Sluggishness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Swelling | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vaccination site pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vaccination site rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hepatobiliary disorders | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Bile duct stone | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cholelithiasis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hepatic cirrhosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hepatic steatosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Immune system disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Allergic oedema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Allergy to arthropod sting | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Food allergy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Seasonal allergy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Infections and infestations | 35 | 0.7 (0.5, 1.0) | 2.9 | (2.0, 4.0) | 42 | 0.9 (0.6, 1.2) | 3.9 | (2.8, 5.3) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Abscess | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Acute sinusitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Adenoiditis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Appendicitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Appendicitis perforated | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Arthritis infective | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Candida infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Cellulitis | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Conjunctivitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Conjunctivitis bacterial | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cystitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Device related infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Diverticulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Ear infection | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Empyema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Epididymitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Eye infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Groin abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hand-foot-and-mouth disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Helicobacter infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Herpes zoster | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Hordeolum | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Infected dermal cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Kidney infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Latent tuberculosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Mastitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Onychomycosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Oral herpes | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Otitis externa | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Otitis media | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Otitis media acute | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Peritonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Rhinitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Salmonellosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Sepsis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Septic shock | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Sinusitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Tooth abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Tooth infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Urinary tract infection | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.7) | 9 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.6) |
| Varicella zoster virus infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vestibular neuronitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vulvovaginal mycotic infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injury, poisoning and procedural complications | 24 | 0.5 (0.3, 0.7) | 2.0 | (1.3, 2.9) | 35 | 0.7 (0.5, 1.0) | 3.3 | (2.3, 4.6) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Animal bite | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Ankle fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Arthropod sting | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Bone contusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Burns third degree | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cartilage injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Concussion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Contusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Corneal abrasion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Craniocerebral injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Exposure during pregnancy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Fall | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 10 | 0.2 (0.1, 0.4) | 0.9 | (0.5, 1.7) |
| Head injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hip fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Humerus fracture | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Joint injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Ligament rupture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ligament sprain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Limb crushing injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Limb injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Meniscus injury | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Muscle strain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Musculoskeletal injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Neck injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Periorbital haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Post procedural haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Procedural pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Road traffic accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Skin abrasion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Skin laceration | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Stoma complication | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Stress fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Tendon rupture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Tibia fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Tooth fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Wrist fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Investigations | 35 | 0.7 (0.5, 1.0) | 2.9 | (2.0, 4.0) | 13 | 0.3 (0.1, 0.5) | 1.2 | (0.7, 2.1) |
| Alpha 1 foetoprotein increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Antinuclear antibody positive | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Blood cholesterol increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Blood creatinine increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Blood glucose increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Blood pressure increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Body temperature increased | 30 | 0.6 (0.4, 0.9) | 2.5 | (1.7, 3.5) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Heart rate increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Hepatic enzyme increased | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Inflammatory marker increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lipase increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Prostatic specific antigen increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Respiratory rate increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Metabolism and nutrition disorders | 17 | 0.4 (0.2, 0.6) | 1.4 | (0.8, 2.2) | 12 | 0.3 (0.1, 0.4) | 1.1 | (0.6, 2.0) |
| Decreased appetite | 7 | 0.1 (0.1, 0.3) | 0.6 | (0.2, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dehydration | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Diabetes mellitus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Diabetic ketoacidosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Glucose tolerance impaired | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Gout | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Hypercholesterolaemia | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hypokalaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hyponatraemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Iron deficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Type 2 diabetes mellitus | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Vitamin D deficiency | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Musculoskeletal and connective tissue disorders | 343 | 7.2 (6.5, 8.0) | 28.2 | (25.3, 31.3) | 51 | 1.1 (0.8, 1.4) | 4.8 | (3.6, 6.3) |
| Arthralgia | 39 | 0.8 (0.6, 1.1) | 3.2 | (2.3, 4.4) | 16 | 0.3 (0.2, 0.5) | 1.5 | (0.9, 2.4) |
| Arthritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Back pain | 8 | 0.2 (0.1, 0.3) | 0.7 | (0.3, 1.3) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Bone cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Bone pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Foot deformity | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Groin pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Joint effusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Joint stiffness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Joint swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Metatarsalgia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Muscle fatigue | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Muscle swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Muscular weakness | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Musculoskeletal chest pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Musculoskeletal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Musculoskeletal pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Musculoskeletal stiffness | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Myalgia | 233 | 4.9 (4.3, 5.5) | 19.1 | (16.7, 21.7) | 18 | 0.4 (0.2, 0.6) | 1.7 | (1.0, 2.7) |
| Neck pain | 10 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Osteoarthritis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Osteoporosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pain in extremity | 56 | 1.2 (0.9, 1.5) | 4.6 | (3.5, 6.0) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Pain in jaw | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Psoriatic arthropathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Rotator cuff syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Scoliosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Spinal stenosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Synovial cyst | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Tendonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Trigger finger | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 15 | 0.3 (0.2, 0.5) | 1.2 | (0.7, 2.0) | 10 | 0.2 (0.1, 0.4) | 0.9 | (0.5, 1.7) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Basal cell carcinoma | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Benign neoplasm of thyroid gland | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Breast cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Focal nodular hyperplasia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Granular cell tumour | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Malignant melanoma | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Melanocytic naevus | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Prostate cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Skin cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Squamous cell carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Squamous cell carcinoma of skin | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Uterine leiomyoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nervous system disorders | 279 | 5.9 (5.2, 6.6) | 22.9 | (20.3, 25.7) | 63 | 1.3 (1.0, 1.7) | 5.9 | (4.6, 7.6) |
| Altered state of consciousness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Bell's palsy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Carpal tunnel syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cervical radiculopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cervicobrachial syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dizziness | 7 | 0.1 (0.1, 0.3) | 0.6 | (0.2, 1.2) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Dysgeusia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Headache | 245 | 5.1 (4.5, 5.8) | 20.1 | (17.7, 22.8) | 47 | 1.0 (0.7, 1.3) | 4.4 | (3.2, 5.9) |
| Hyperaesthesia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Hypoaesthesia | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hypotonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Lethargy | 12 | 0.3 (0.1, 0.4) | 1.0 | (0.5, 1.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Migraine | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Migraine with aura | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nerve compression | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Neuralgic amyotrophy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Paraesthesia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Parosmia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Sciatica | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Somnolence | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Syncope | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Taste disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Tension headache | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Tremor | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pregnancy, puerperium and perinatal conditions | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abortion spontaneous | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pregnancy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Psychiatric disorders | 17 | 0.4 (0.2, 0.6) | 1.4 | (0.8, 2.2) | 15 | 0.3 (0.2, 0.5) | 1.4 | (0.8, 2.3) |
| Abnormal dreams | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Adjustment disorder with mixed anxiety and depressed mood | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Alcoholism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Anxiety | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Attention deficit hyperactivity disorder | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Depression | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Generalised anxiety disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Insomnia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Mood altered | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nightmare | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Poor quality sleep | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Stress | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Renal and urinary disorders | 11 | 0.2 (0.1, 0.4) | 0.9 | (0.5, 1.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Cystitis haemorrhagic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dysuria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Haematuria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nephrolithiasis | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Renal colic | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Renal cyst | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Stress urinary incontinence | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Urinary incontinence | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Reproductive system and breast disorders | 8 | 0.2 (0.1, 0.3) | 0.7 | (0.3, 1.3) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Atrophic vulvovaginitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Breast calcifications | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Endometriosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Heavy menstrual bleeding | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Intermenstrual bleeding | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Menstruation irregular | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ovarian cyst | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Prostatitis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Scrotal disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Respiratory, thoracic and mediastinal disorders | 14 | 0.3 (0.2, 0.5) | 1.1 | (0.6, 1.9) | 16 | 0.3 (0.2, 0.5) | 1.5 | (0.9, 2.4) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Asthma | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Asthma exercise induced | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dry throat | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Epistaxis | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nasal congestion | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Nasal polyps | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pharyngeal swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pleural effusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pulmonary congestion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Respiratory failure | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Rhinorrhoea | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Sinus congestion | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Sleep apnoea syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Sneezing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Skin and subcutaneous tissue disorders | 24 | 0.5 (0.3, 0.7) | 2.0 | (1.3, 2.9) | 12 | 0.3 (0.1, 0.4) | 1.1 | (0.6, 2.0) |
| Alopecia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cold sweat | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dermal cyst | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Dermatitis allergic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dermatitis contact | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dry skin | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Erythema | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hyperhidrosis | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intertrigo | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Night sweats | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pruritus | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Rash | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Rash erythematous | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Rash papular | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Urticaria | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Xanthoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Surgical and medical procedures | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abortion induced | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Bunion operation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vascular disorders | 7 | 0.1 (0.1, 0.3) | 0.6 | (0.2, 1.2) | 12 | 0.3 (0.1, 0.4) | 1.1 | (0.6, 2.0) |
| Deep vein thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Flushing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Haematoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.72. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Hot flush | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Hypertension | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Hypotension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Peripheral venous disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |

Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: MedDRA (v24.1) coding dictionary applied.
Note: Participants whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19.
Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (14:26)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_base_6m_saf

## 14.73. Incidence Rates of at Least 1 Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – HIV-Positive Participants – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=26, TE[b]=0.1) | | | | Placebo (N[a]=24, TE[b]=0.1) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 1 | 3.8 (0.1, 19.6) | 11.5 | (0.3, 64.1) | 1 | 4.2 (0.1, 21.1) | 19.7 | (0.5, 109.5) |
| General disorders and administration site conditions | 1 | 3.8 (0.1, 19.6) | 11.5 | (0.3, 64.1) | 1 | 4.2 (0.1, 21.1) | 19.7 | (0.5, 109.5) |
| Fatigue | 0 | 0.0 (0.0, 13.2) | 0.0 | (0.0, 42.4) | 1 | 4.2 (0.1, 21.1) | 19.7 | (0.5, 109.5) |
| Pain | 1 | 3.8 (0.1, 19.6) | 11.5 | (0.3, 64.1) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Nervous system disorders | 1 | 3.8 (0.1, 19.6) | 11.5 | (0.3, 64.1) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |
| Headache | 1 | 3.8 (0.1, 19.6) | 11.5 | (0.3, 64.1) | 0 | 0.0 (0.0, 14.2) | 0.0 | (0.0, 72.5) |

Abbreviation: HIV = human immunodeficiency virus.
Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (20:53)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_all_6m_hiv_saf

## 14.74. Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=10.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 1206 | 23.9 (22.7, 25.1) | 92.5 | (87.3, 97.8) | 213 | 4.2 (3.7, 4.8) | 18.9 | (16.4, 21.6) |
| Blood and lymphatic system disorders | 138 | 2.7 (2.3, 3.2) | 10.6 | (8.9, 12.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Lymph node pain | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lymphadenitis | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lymphadenopathy | 134 | 2.7 (2.2, 3.1) | 10.3 | (8.6, 12.2) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Lymphopenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Neutropenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Thrombocytopenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cardiac disorders | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Acute myocardial infarction | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Palpitations | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Tachycardia | 2 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ear and labyrinth disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ear pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vertigo | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Eye disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Diplopia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Eye pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Macular degeneration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Photophobia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Gastrointestinal disorders | 82 | 1.6 (1.3, 2.0) | 6.3 | (5.0, 7.8) | 29 | 0.6 (0.4, 0.8) | 2.6 | (1.7, 3.7) |
| Abdominal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abdominal pain | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abdominal pain upper | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Constipation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Diarrhoea | 26 | 0.5 (0.3, 0.8) | 2.0 | (1.3, 2.9) | 13 | 0.3 (0.1, 0.4) | 1.2 | (0.6, 2.0) |
| Dry mouth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dyspepsia | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Gingival pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hypoaesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hypoaesthesia teeth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nausea | 50 | 1.0 (0.7, 1.3) | 3.8 | (2.8, 5.1) | 16 | 0.3 (0.2, 0.5) | 1.4 | (0.8, 2.3) |
| Paraesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Vomiting | 12 | 0.2 (0.1, 0.4) | 0.9 | (0.5, 1.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |

## 14.74. Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=10.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| General disorders and administration site conditions | 1076 | 21.3 (20.2, 22.4) | 82.5 | (77.6, 87.6) | 153 | 3.0 (2.6, 3.6) | 13.6 | (11.5, 15.9) |
| Asthenia | 8 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.2) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Axillary pain | 12 | 0.2 (0.1, 0.4) | 0.9 | (0.5, 1.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Chest discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Chest pain | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Chills | 237 | 4.7 (4.1, 5.3) | 18.2 | (15.9, 20.6) | 10 | 0.2 (0.1, 0.4) | 0.9 | (0.4, 1.6) |
| Fatigue | 370 | 7.3 (6.6, 8.1) | 28.4 | (25.5, 31.4) | 62 | 1.2 (0.9, 1.6) | 5.5 | (4.2, 7.0) |
| Feeling abnormal | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Feeling hot | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site bruising | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Injection site discomfort | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site erythema | 22 | 0.4 (0.3, 0.7) | 1.7 | (1.1, 2.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site hypoaesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site induration | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site inflammation | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site irritation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site lymphadenopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injection site oedema | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site pain | 657 | 13.0 (12.1, 14.0) | 50.4 | (46.6, 54.4) | 80 | 1.6 (1.3, 2.0) | 7.1 | (5.6, 8.8) |
| Injection site paraesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site pruritus | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site reaction | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site swelling | 21 | 0.4 (0.3, 0.6) | 1.6 | (1.0, 2.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injection site vesicles | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Injection site warmth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Malaise | 35 | 0.7 (0.5, 1.0) | 2.7 | (1.9, 3.7) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Pain | 136 | 2.7 (2.3, 3.2) | 10.4 | (8.7, 12.3) | 16 | 0.3 (0.2, 0.5) | 1.4 | (0.8, 2.3) |
| Peripheral swelling | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pyrexia | 250 | 4.9 (4.4, 5.6) | 19.2 | (16.9, 21.7) | 7 | 0.1 (0.1, 0.3) | 0.6 | (0.2, 1.3) |
| Sluggishness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Swelling | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vaccination site pain | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.74. Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=10.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Vaccination site rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Immune system disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Allergic oedema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injury, poisoning and procedural complications | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Limb injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Periorbital haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Procedural pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Investigations | 32 | 0.6 (0.4, 0.9) | 2.5 | (1.7, 3.5) | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Blood glucose increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Body temperature increased | 30 | 0.6 (0.4, 0.8) | 2.3 | (1.6, 3.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Heart rate increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hepatic enzyme increased | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Metabolism and nutrition disorders | 8 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Decreased appetite | 7 | 0.1 (0.1, 0.3) | 0.5 | (0.2, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dehydration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Musculoskeletal and connective tissue disorders | 322 | 6.4 (5.7, 7.1) | 24.7 | (22.1, 27.5) | 30 | 0.6 (0.4, 0.9) | 2.7 | (1.8, 3.8) |
| Arthralgia | 36 | 0.7 (0.5, 1.0) | 2.8 | (1.9, 3.8) | 8 | 0.2 (0.1, 0.3) | 0.7 | (0.3, 1.4) |
| Back pain | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Bone pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Groin pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Joint stiffness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Muscle fatigue | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Muscle swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Muscular weakness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Musculoskeletal discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Musculoskeletal stiffness | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Myalgia | 240 | 4.7 (4.2, 5.4) | 18.4 | (16.1, 20.9) | 20 | 0.4 (0.2, 0.6) | 1.8 | (1.1, 2.7) |
| Neck pain | 8 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.2) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pain in extremity | 53 | 1.0 (0.8, 1.4) | 4.1 | (3.0, 5.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pain in jaw | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.74. Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=10.3) | | | |
| | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Synovial cyst | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Tendonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nervous system disorders | 285 | 5.6 (5.0, 6.3) | 21.8 | (19.4, 24.5) | 54 | 1.1 (0.8, 1.4) | 4.8 | (3.6, 6.2) |
| Altered state of consciousness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dizziness | 8 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.2) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Dysgeusia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Headache | 259 | 5.1 (4.5, 5.8) | 19.9 | (17.5, 22.4) | 46 | 0.9 (0.7, 1.2) | 4.1 | (3.0, 5.4) |
| Hyperaesthesia | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hypoaesthesia | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lethargy | 12 | 0.2 (0.1, 0.4) | 0.9 | (0.5, 1.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Migraine | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Neuralgic amyotrophy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Paraesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Parosmia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Somnolence | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Syncope | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Taste disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Tremor | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Psychiatric disorders | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Abnormal dreams | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Generalised anxiety disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Insomnia | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Nightmare | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Poor quality sleep | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Renal and urinary disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dysuria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Reproductive system and breast disorders | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Breast pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Heavy menstrual bleeding | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Respiratory, thoracic and mediastinal disorders | 6 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.0) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Dry throat | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Nasal congestion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.74. Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=10.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Rhinorrhoea | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Sinus congestion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Sneezing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Throat tightness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Skin and subcutaneous tissue disorders | 15 | 0.3 (0.2, 0.5) | 1.1 | (0.6, 1.9) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Cold sweat | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dermatitis allergic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hyperhidrosis | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Night sweats | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pruritus | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Rash papular | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Urticaria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Vascular disorders | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Flushing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Hot flush | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 01APR2022 (02:58)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ub3IA/C4591031_A_SBLA/adae_s131_6m_rel_saf

## 14.75. Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 753 | 26.9 (25.2, 28.5) | 103.2 | (96.0, 110.9) | 127 | 4.6 (3.8, 5.4) | 19.9 | (16.5, 23.6) |
| Blood and lymphatic system disorders | 115 | 4.1 (3.4, 4.9) | 15.8 | (13.0, 18.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Lymph node pain | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Lymphadenitis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Lymphadenopathy | 111 | 4.0 (3.3, 4.7) | 15.2 | (12.5, 18.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Lymphopenia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Neutropenia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Thrombocytopenia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Cardiac disorders | 5 | 0.2 (0.1, 0.4) | 0.7 | (0.2, 1.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Palpitations | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Tachycardia | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Ear and labyrinth disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Vertigo | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Eye disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Diplopia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Eye pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Photophobia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Gastrointestinal disorders | 47 | 1.7 (1.2, 2.2) | 6.4 | (4.7, 8.6) | 16 | 0.6 (0.3, 0.9) | 2.5 | (1.4, 4.1) |
| Abdominal pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Abdominal pain upper | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Constipation | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Diarrhoea | 18 | 0.6 (0.4, 1.0) | 2.5 | (1.5, 3.9) | 7 | 0.3 (0.1, 0.5) | 1.1 | (0.4, 2.3) |
| Dry mouth | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Dyspepsia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Hypoaesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Hypoaesthesia teeth | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Nausea | 23 | 0.8 (0.5, 1.2) | 3.2 | (2.0, 4.7) | 9 | 0.3 (0.1, 0.6) | 1.4 | (0.6, 2.7) |
| Paraesthesia oral | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Vomiting | 7 | 0.2 (0.1, 0.5) | 1.0 | (0.4, 2.0) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| General disorders and administration site conditions | 666 | 23.8 (22.2, 25.4) | 91.3 | (84.5, 98.5) | 90 | 3.2 (2.6, 4.0) | 14.1 | (11.3, 17.3) |
| Asthenia | 5 | 0.2 (0.1, 0.4) | 0.7 | (0.2, 1.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Axillary pain | 9 | 0.3 (0.1, 0.6) | 1.2 | (0.6, 2.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Chest discomfort | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |

## 14.75. Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Chest pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Chills | 152 | 5.4 (4.6, 6.3) | 20.8 | (17.7, 24.4) | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) |
| Fatigue | 209 | 7.5 (6.5, 8.5) | 28.7 | (24.9, 32.8) | 36 | 1.3 (0.9, 1.8) | 5.6 | (3.9, 7.8) |
| Feeling abnormal | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Feeling hot | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site bruising | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Injection site discomfort | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site erythema | 10 | 0.4 (0.2, 0.7) | 1.4 | (0.7, 2.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site induration | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site inflammation | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site oedema | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site pain | 417 | 14.9 (13.6, 16.2) | 57.2 | (51.8, 62.9) | 50 | 1.8 (1.3, 2.4) | 7.8 | (5.8, 10.3) |
| Injection site paraesthesia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site pruritus | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site reaction | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injection site swelling | 11 | 0.4 (0.2, 0.7) | 1.5 | (0.8, 2.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Malaise | 25 | 0.9 (0.6, 1.3) | 3.4 | (2.2, 5.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pain | 81 | 2.9 (2.3, 3.6) | 11.1 | (8.8, 13.8) | 7 | 0.3 (0.1, 0.5) | 1.1 | (0.4, 2.3) |
| Peripheral swelling | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Pyrexia | 157 | 5.6 (4.8, 6.5) | 21.5 | (18.3, 25.2) | 4 | 0.1 (0.0, 0.4) | 0.6 | (0.2, 1.6) |
| Sluggishness | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Swelling | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Vaccination site pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Vaccination site rash | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Immune system disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Allergic oedema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Injury, poisoning and procedural complications | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Procedural pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Investigations | 20 | 0.7 (0.4, 1.1) | 2.7 | (1.7, 4.2) | 4 | 0.1 (0.0, 0.4) | 0.6 | (0.2, 1.6) |
| Body temperature increased | 19 | 0.7 (0.4, 1.1) | 2.6 | (1.6, 4.1) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Heart rate increased | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Hepatic enzyme increased | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |

## 14.75. Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Metabolism and nutrition disorders | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Decreased appetite | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Musculoskeletal and connective tissue disorders | 201 | 7.2 (6.2, 8.2) | 27.6 | (23.9, 31.6) | 18 | 0.6 (0.4, 1.0) | 2.8 | (1.7, 4.4) |
| Arthralgia | 19 | 0.7 (0.4, 1.1) | 2.6 | (1.6, 4.1) | 4 | 0.1 (0.0, 0.4) | 0.6 | (0.2, 1.6) |
| Back pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Bone pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Muscle fatigue | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Muscular weakness | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Musculoskeletal stiffness | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Myalgia | 157 | 5.6 (4.8, 6.5) | 21.5 | (18.3, 25.2) | 14 | 0.5 (0.3, 0.8) | 2.2 | (1.2, 3.7) |
| Neck pain | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Pain in extremity | 25 | 0.9 (0.6, 1.3) | 3.4 | (2.2, 5.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Pain in jaw | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Synovial cyst | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Nervous system disorders | 176 | 6.3 (5.4, 7.2) | 24.1 | (20.7, 28.0) | 31 | 1.1 (0.8, 1.6) | 4.8 | (3.3, 6.9) |
| Dizziness | 7 | 0.2 (0.1, 0.5) | 1.0 | (0.4, 2.0) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Headache | 160 | 5.7 (4.9, 6.6) | 21.9 | (18.7, 25.6) | 27 | 1.0 (0.6, 1.4) | 4.2 | (2.8, 6.1) |
| Hyperaesthesia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Hypoaesthesia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Lethargy | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Migraine | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Neuralgic amyotrophy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Paraesthesia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Parosmia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Somnolence | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Taste disorder | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Tremor | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Psychiatric disorders | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Abnormal dreams | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Generalised anxiety disorder | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Insomnia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Nightmare | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Reproductive system and breast disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |

## 14.75. Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Heavy menstrual bleeding | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Respiratory, thoracic and mediastinal disorders | 5 | 0.2 (0.1, 0.4) | 0.7 | (0.2, 1.6) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Dry throat | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Nasal congestion | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Rhinorrhoea | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Sneezing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Throat tightness | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Skin and subcutaneous tissue disorders | 9 | 0.3 (0.1, 0.6) | 1.2 | (0.6, 2.3) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.4) |
| Cold sweat | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Dermatitis allergic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Hyperhidrosis | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Night sweats | 4 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Pruritus | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Rash papular | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Vascular disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Flushing | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Hot flush | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (20:59)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_6m_rel_age_saf

## 14.76. Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 453 | 20.1 (18.5, 21.8) | 78.8 | (71.7, 86.4) | 86 | 3.8 (3.1, 4.7) | 17.6 | (14.1, 21.7) |
| Blood and lymphatic system disorders | 23 | 1.0 (0.6, 1.5) | 4.0 | (2.5, 6.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Lymphadenopathy | 23 | 1.0 (0.6, 1.5) | 4.0 | (2.5, 6.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Cardiac disorders | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Acute myocardial infarction | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Ear and labyrinth disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Ear pain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Eye disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Macular degeneration | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Gastrointestinal disorders | 35 | 1.6 (1.1, 2.2) | 6.1 | (4.2, 8.5) | 13 | 0.6 (0.3, 1.0) | 2.7 | (1.4, 4.5) |
| Abdominal discomfort | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Abdominal pain upper | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Diarrhoea | 8 | 0.4 (0.2, 0.7) | 1.4 | (0.6, 2.7) | 6 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.7) |
| Dyspepsia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Gingival pain | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Nausea | 27 | 1.2 (0.8, 1.7) | 4.7 | (3.1, 6.8) | 7 | 0.3 (0.1, 0.6) | 1.4 | (0.6, 2.9) |
| Vomiting | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| General disorders and administration site conditions | 410 | 18.2 (16.6, 19.9) | 71.3 | (64.6, 78.5) | 63 | 2.8 (2.2, 3.6) | 12.9 | (9.9, 16.5) |
| Asthenia | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Axillary pain | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Chills | 85 | 3.8 (3.0, 4.6) | 14.8 | (11.8, 18.3) | 4 | 0.2 (0.0, 0.5) | 0.8 | (0.2, 2.1) |
| Fatigue | 161 | 7.2 (6.1, 8.3) | 28.0 | (23.8, 32.7) | 26 | 1.2 (0.8, 1.7) | 5.3 | (3.5, 7.8) |
| Injection site bruising | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site erythema | 12 | 0.5 (0.3, 0.9) | 2.1 | (1.1, 3.6) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site hypoaesthesia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site inflammation | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site irritation | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site lymphadenopathy | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Injection site oedema | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site pain | 240 | 10.7 (9.4, 12.0) | 41.7 | (36.6, 47.4) | 30 | 1.3 (0.9, 1.9) | 6.1 | (4.1, 8.8) |
| Injection site pruritus | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |

## 14.76. Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Injection site rash | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site reaction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site swelling | 10 | 0.4 (0.2, 0.8) | 1.7 | (0.8, 3.2) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Injection site vesicles | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injection site warmth | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Malaise | 10 | 0.4 (0.2, 0.8) | 1.7 | (0.8, 3.2) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Pain | 55 | 2.4 (1.8, 3.2) | 9.6 | (7.2, 12.4) | 9 | 0.4 (0.2, 0.8) | 1.8 | (0.8, 3.5) |
| Peripheral swelling | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Pyrexia | 93 | 4.1 (3.3, 5.0) | 16.2 | (13.1, 19.8) | 3 | 0.1 (0.0, 0.4) | 0.6 | (0.1, 1.8) |
| Swelling | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Injury, poisoning and procedural complications | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Limb injury | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Periorbital haemorrhage | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Investigations | 12 | 0.5 (0.3, 0.9) | 2.1 | (1.1, 3.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Blood glucose increased | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Body temperature increased | 11 | 0.5 (0.2, 0.9) | 1.9 | (1.0, 3.4) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Hepatic enzyme increased | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Metabolism and nutrition disorders | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Decreased appetite | 4 | 0.2 (0.0, 0.5) | 0.7 | (0.2, 1.8) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Dehydration | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Musculoskeletal and connective tissue disorders | 121 | 5.4 (4.5, 6.4) | 21.0 | (17.5, 25.1) | 12 | 0.5 (0.3, 0.9) | 2.5 | (1.3, 4.3) |
| Arthralgia | 17 | 0.8 (0.4, 1.2) | 3.0 | (1.7, 4.7) | 4 | 0.2 (0.0, 0.5) | 0.8 | (0.2, 2.1) |
| Back pain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Groin pain | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Joint stiffness | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Muscle swelling | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Musculoskeletal discomfort | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Myalgia | 83 | 3.7 (2.9, 4.6) | 14.4 | (11.5, 17.9) | 6 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.7) |
| Neck pain | 4 | 0.2 (0.0, 0.5) | 0.7 | (0.2, 1.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pain in extremity | 28 | 1.2 (0.8, 1.8) | 4.9 | (3.2, 7.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Tendonitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Nervous system disorders | 109 | 4.8 (4.0, 5.8) | 19.0 | (15.6, 22.9) | 23 | 1.0 (0.7, 1.5) | 4.7 | (3.0, 7.1) |

## 14.76. Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Altered state of consciousness | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Dizziness | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Dysgeusia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Headache | 99 | 4.4 (3.6, 5.3) | 17.2 | (14.0, 21.0) | 19 | 0.8 (0.5, 1.3) | 3.9 | (2.3, 6.1) |
| Hyperaesthesia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Hypoaesthesia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Lethargy | 8 | 0.4 (0.2, 0.7) | 1.4 | (0.6, 2.7) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Paraesthesia | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Syncope | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Psychiatric disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Insomnia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Poor quality sleep | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Renal and urinary disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Dysuria | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Reproductive system and breast disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Breast pain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Rhinorrhoea | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Sinus congestion | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Skin and subcutaneous tissue disorders | 6 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Hyperhidrosis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Night sweats | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Pruritus | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Rash | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Urticaria | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Vascular disorders | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Flushing | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |

## 14.76. Incidence Rates of at Least 1 Related Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (20:59)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_6m_rel_age_saf

## 14.77. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 39 | 0.8 (0.5, 1.1) | 3.0 | (2.1, 4.1) | 35 | 0.7 (0.5, 1.0) | 3.1 | (2.2, 4.3) |
| Cardiac disorders | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Acute myocardial infarction | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Atrial fibrillation | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cardiac failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pericarditis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Tachycardia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Endocrine disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Goitre | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Gastrointestinal disorders | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Gastric fistula | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| General disorders and administration site conditions | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Chest discomfort | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hepatobiliary disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Bile duct stone | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Immune system disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Food allergy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Infections and infestations | 8 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.2) | 7 | 0.1 (0.1, 0.3) | 0.6 | (0.2, 1.3) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Appendicitis | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Appendicitis perforated | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Device related infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |

## 14.77. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Diverticulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Empyema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Salmonellosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Sepsis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Septic shock | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Urinary tract infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injury, poisoning and procedural complications | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hip fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Humerus fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ligament rupture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Stoma complication | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Investigations | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hepatic enzyme increased | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Musculoskeletal and connective tissue disorders | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Back pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 6 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.0) | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

## 14.77. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Prostate cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nervous system disorders | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Syncope | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pregnancy, puerperium and perinatal conditions | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abortion spontaneous | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Psychiatric disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Renal and urinary disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Nephrolithiasis | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Renal cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Reproductive system and breast disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 7 | 0.1 (0.1, 0.3) | 0.6 | (0.2, 1.3) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pleural effusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Respiratory failure | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Vascular disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hypertension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

## 14.77. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 01APR2022 (02:56)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ser_all_6m_saf

## 14.78. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 15 | 0.5 (0.3, 0.9) | 2.1 | (1.2, 3.4) | 14 | 0.5 (0.3, 0.8) | 2.2 | (1.2, 3.7) |
| Cardiac disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Tachycardia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Endocrine disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Goitre | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Gastrointestinal disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Gastric fistula | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Small intestinal obstruction | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| General disorders and administration site conditions | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Hepatobiliary disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Bile duct stone | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Infections and infestations | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Appendicitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Septic shock | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injury, poisoning and procedural complications | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Humerus fracture | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Ligament rupture | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Stoma complication | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Investigations | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Hepatic enzyme increased | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Musculoskeletal and connective tissue disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Back pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |

## 14.78. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Nervous system disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Pregnancy, puerperium and perinatal conditions | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Abortion spontaneous | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Psychiatric disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Renal and urinary disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Reproductive system and breast disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Respiratory, thoracic and mediastinal disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Vascular disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Hypertension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:16)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ser_age_6m_saf

## 14.79. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 24 | 1.1 (0.7, 1.6) | 4.2 | (2.7, 6.2) | 21 | 0.9 (0.6, 1.4) | 4.3 | (2.7, 6.6) |
| Cardiac disorders | 4 | 0.2 (0.0, 0.5) | 0.7 | (0.2, 1.8) | 3 | 0.1 (0.0, 0.4) | 0.6 | (0.1, 1.8) |
| Acute myocardial infarction | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Atrial fibrillation | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Cardiac failure | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pericarditis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Endocrine disorders | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Goitre | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Gastrointestinal disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| General disorders and administration site conditions | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Chest discomfort | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Immune system disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Food allergy | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Infections and infestations | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Appendicitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Appendicitis perforated | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Device related infection | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Diverticulitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Empyema | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Salmonellosis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Sepsis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Urinary tract infection | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Injury, poisoning and procedural complications | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Hip fracture | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Investigations | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |

## 14.79. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Hepatic enzyme increased | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Musculoskeletal and connective tissue disorders | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Back pain | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Prostate cancer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Nervous system disorders | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Syncope | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Renal and urinary disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Renal cyst | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pleural effusion | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Respiratory failure | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |

## 14.79. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:16)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ser_age_6m_saf

## 14.80. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | | Placebo (N[a]=5020, TE[b]=11.3) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 6 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) |
| Cardiac disorders | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Acute myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Infections and infestations | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Device related infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Septic shock | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.1) | 0.2 | (0.0, 0.6) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Nervous system disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Respiratory, thoracic and mediastinal disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:49)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_6m_life_saf

## 14.81. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Infections and infestations | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Septic shock | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (21:03)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_6m_life_age_saf

## 14.82. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term, by Age Group – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Cardiac disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Acute myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Infections and infestations | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Device related infection | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Nervous system disorders | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Respiratory, thoracic and mediastinal disorders | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (21:03)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBLA/C4591031_A_SBLA/adae_s130_6m_life_age_saf

## 14.83. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to the Cutoff Date, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2496, TE[b]=7.7) | | | |
| **Adverse Event** | **n[c] (%)** | **% (95% CI[d])** | **IR (/100 PYs[e])** | **(95% CI[f])** |
| Any event | 38 | 1.5 (1.1, 2.1) | 4.9 | (3.5, 6.7) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Severe | 8 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.0) |
| Life-threatening | 5 | 0.2 (0.1, 0.5) | 0.6 | (0.2, 1.5) |
| Any serious adverse event | 17 | 0.7 (0.4, 1.1) | 2.2 | (1.3, 3.5) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Severe | 8 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.0) |
| Life-threatening | 5 | 0.2 (0.1, 0.5) | 0.6 | (0.2, 1.5) |
| Any nonserious adverse event | 24 | 1.0 (0.6, 1.4) | 3.1 | (2.0, 4.6) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Severe | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Severe | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Death | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (09:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_subBIA/C4591031_A_SBLA/adae_s091_cut_age_bnt_o_sf

## 14.84. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to the Cutoff Date, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1993, TE[b]=6.5) | | | |
| Adverse Event | n[c] (%) | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 36 | 1.8 (1.3, 2.5) | 5.6 | (3.9, 7.7) |
| Related[g] | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Severe | 9 | 0.5 (0.2, 0.9) | 1.4 | (0.6, 2.6) |
| Life-threatening | 4 | 0.2 (0.1, 0.5) | 0.6 | (0.2, 1.6) |
| Any serious adverse event | 19 | 1.0 (0.6, 1.5) | 2.9 | (1.8, 4.6) |
| Related[g] | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Severe | 9 | 0.5 (0.2, 0.9) | 1.4 | (0.6, 2.6) |
| Life-threatening | 4 | 0.2 (0.1, 0.5) | 0.6 | (0.2, 1.6) |
| Any nonserious adverse event | 21 | 1.1 (0.7, 1.6) | 3.2 | (2.0, 5.0) |
| Related[g] | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Severe | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.1) |
| Life-threatening | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Any adverse event leading to withdrawal | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Related[g] | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Severe | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Life-threatening | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Death | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.1) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (09:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ub3IA/C4591031_A_SBLA/adae_s091_cut_age_bnt_o_sf

## 14.85. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4489, TE[b]=14.2) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 74 | 1.6 (1.3, 2.1) | 5.2 | (4.1, 6.5) |
| Blood and lymphatic system disorders | 2 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.5) |
| Leukocytosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Sickle cell anaemia with crisis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Cardiac disorders | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.7) |
| Acute myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Atrial fibrillation | 2 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.5) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Gastrointestinal disorders | 9 | 0.2 (0.1, 0.4) | 0.6 | (0.3, 1.2) |
| Colitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Dental caries | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Gastritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Gastrointestinal haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Hiatus hernia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Intestinal perforation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Lower gastrointestinal haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nausea | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pancreatic pseudocyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pancreatitis acute | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| General disorders and administration site conditions | 8 | 0.2 (0.1, 0.4) | 0.6 | (0.2, 1.1) |
| Asthenia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Chest pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Death | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injection site pain | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Non-cardiac chest pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Hepatobiliary disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Bile duct stone | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Cholelithiasis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Hepatomegaly | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Infections and infestations | 14 | 0.3 (0.2, 0.5) | 1.0 | (0.5, 1.7) |
| Acute sinusitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Anal fistula infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Appendicitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Cellulitis | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Cystitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

## 14.85. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4489, TE[b]=14.2) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Gastroenteritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Herpes zoster | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Liver abscess | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Lyme disease | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Onychomycosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Osteomyelitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Otitis media | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Peritonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Tooth infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Urinary tract infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injury, poisoning and procedural complications | 7 | 0.2 (0.1, 0.3) | 0.5 | (0.2, 1.0) |
| Arthropod bite | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Arthropod sting | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Clavicle fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Craniocerebral injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Fall | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Procedural nausea | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Rib fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Road traffic accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Subdural haematoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Wrist fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Investigations | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Blood cholesterol increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Metabolism and nutrition disorders | 2 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.5) |
| Decreased appetite | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Hypervolaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Musculoskeletal and connective tissue disorders | 6 | 0.1 (0.0, 0.3) | 0.4 | (0.2, 0.9) |
| Arthralgia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Back pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Joint swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Musculoskeletal chest pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Myalgia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Spondylolisthesis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 10 | 0.2 (0.1, 0.4) | 0.7 | (0.3, 1.3) |
| Basal cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Brain neoplasm | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

## 14.85. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4489, TE[b]=14.2) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Breast cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Lipoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Meningioma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nervous system neoplasm | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Prostate cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Squamous cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Uterine cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nervous system disorders | 8 | 0.2 (0.1, 0.4) | 0.6 | (0.2, 1.1) |
| Cerebral haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Headache | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Intracranial aneurysm | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Presyncope | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Seizure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Syncope | 2 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.5) |
| Pregnancy, puerperium and perinatal conditions | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pregnancy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Psychiatric disorders | 2 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.5) |
| Bipolar disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Depression | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Renal and urinary disorders | 2 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.5) |
| End stage renal disease | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Reproductive system and breast disorders | 2 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.5) |
| Breast mass | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Menopausal symptoms | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Respiratory, thoracic and mediastinal disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Asthma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Negative pressure pulmonary oedema | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Upper-airway cough syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Skin and subcutaneous tissue disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Rash maculo-papular | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Vascular disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Hypertension | 2 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.5) |
| Shock haemorrhagic | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

## 14.85. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) ($N^a$=4489, $TE^b$=14.2) | | | |
| System Organ Class<br>Preferred Term | $n^c$ | % (95% $CI^d$) | IR (/100 $PY^e$) | (95% $CI^f$) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from unblinding date to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (07:56)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_cut_bnt_ol_sar

## 14.86. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to the Cutoff Date, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) ($N^a$=2496, $TE^b$=7.7) | | | |
| Adverse Event | $n^c$ (%) | % (95% $CI^d$) | IR (/100 $PY^e$) | (95% $CI^f$) |
| Any event | 38 | 1.5 (1.1, 2.1) | 4.9 | (3.5, 6.7) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Severe | 8 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.0) |
| Life-threatening | 5 | 0.2 (0.1, 0.5) | 0.6 | (0.2, 1.5) |
| Any serious adverse event | 17 | 0.7 (0.4, 1.1) | 2.2 | (1.3, 3.5) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Severe | 8 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.0) |
| Life-threatening | 5 | 0.2 (0.1, 0.5) | 0.6 | (0.2, 1.5) |
| Any nonserious adverse event | 24 | 1.0 (0.6, 1.4) | 3.1 | (2.0, 4.6) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Severe | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |

## 14.86. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to the Cutoff Date, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2496, TE[b]=7.7) | | | |
| **Adverse Event** | **n[c] (%)** | **% (95% CI[d])** | **IR (/100 PY[e])** | **(95% CI[f])** |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Related[g] | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Severe | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Life-threatening | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) |
| Death | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (09:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s091_cut_age_bnt_o_sf

## 14.87. Incidence Rates of at Least 1 Adverse Event From Unblinding Date to the Cutoff Date, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1993, TE[b]=6.5) | | | |
| Adverse Event | n[c] (%) | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 36 | 1.8 (1.3, 2.5) | 5.6 | (3.9, 7.7) |
| Related[g] | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Severe | 9 | 0.5 (0.2, 0.9) | 1.4 | (0.6, 2.6) |
| Life-threatening | 4 | 0.2 (0.1, 0.5) | 0.6 | (0.2, 1.6) |
| Any serious adverse event | 19 | 1.0 (0.6, 1.5) | 2.9 | (1.8, 4.6) |
| Related[g] | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Severe | 9 | 0.5 (0.2, 0.9) | 1.4 | (0.6, 2.6) |
| Life-threatening | 4 | 0.2 (0.1, 0.5) | 0.6 | (0.2, 1.6) |
| Any nonserious adverse event | 21 | 1.1 (0.7, 1.6) | 3.2 | (2.0, 5.0) |
| Related[g] | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Severe | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.1) |
| Life-threatening | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Any adverse event leading to withdrawal | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Related[g] | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Severe | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Life-threatening | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Death | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.1) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (09:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ub3IA/C4591031_A_SBLA/adae_s091_cut_age_bnt_o_sf

## 14.88. Incidence Rates of at Least 1 Severe Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4489, TE[b]=14.2) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 17 | 0.4 (0.2, 0.6) | 1.2 | (0.7, 1.9) |
| Blood and lymphatic system disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Sickle cell anaemia with crisis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Gastrointestinal disorders | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.8) |
| Gastrointestinal haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Hiatus hernia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Intestinal perforation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Lower gastrointestinal haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pancreatic pseudocyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pancreatitis acute | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Infections and infestations | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.7) |
| Appendicitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Gastroenteritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Liver abscess | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Lyme disease | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Peritonitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injury, poisoning and procedural complications | 2 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.5) |
| Clavicle fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Fall | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Road traffic accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Subdural haematoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Metabolism and nutrition disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Hypervolaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Breast cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nervous system neoplasm | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nervous system disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Renal and urinary disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| End stage renal disease | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Vascular disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Shock haemorrhagic | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

## 14.88. Incidence Rates of at Least 1 Severe Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) ($N^a$=4489, $TE^b$=14.2) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from unblinding date to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (07:56)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_cut_ser_bnt_ol_saf

## 14.89. Incidence Rates of at Least 1 Severe Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) ($N^a$=2496, $TE^b$=7.7) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 8 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.0) |
| Blood and lymphatic system disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Sickle cell anaemia with crisis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Gastrointestinal disorders | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.1) |
| Gastrointestinal haemorrhage | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Intestinal perforation | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Pancreatic pseudocyst | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Pancreatitis acute | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Infections and infestations | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.1) |

## 14.89. Incidence Rates of at Least 1 Severe Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2496, TE[b]=7.7) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Appendicitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Gastroenteritis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Lyme disease | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Peritonitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Nervous system neoplasm | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Vascular disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Shock haemorrhagic | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from unblinding date to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:35)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_sev_age_bnt_ol_saf

## 14.90. Incidence Rates of at Least 1 Severe Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1993, TE[b]=6.5) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 9 | 0.5 (0.2, 0.9) | 1.4 | (0.6, 2.6) |
| Gastrointestinal disorders | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.1) |
| Hiatus hernia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Lower gastrointestinal haemorrhage | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Infections and infestations | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Liver abscess | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Injury, poisoning and procedural complications | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.1) |
| Clavicle fracture | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Fall | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Road traffic accident | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Subdural haematoma | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Metabolism and nutrition disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Hypervolaemia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.1) |
| Breast cancer | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Invasive ductal breast carcinoma | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Nervous system disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Cerebrovascular accident | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Renal and urinary disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| End stage renal disease | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from unblinding date to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:35)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_sev_age_bnt_ol_saf

## 14.91. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=4489, TE[b]=14.2)<br>n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
|---|---|---|---|---|
| Any event | 9 | 0.2 (0.1, 0.4) | 0.6 | (0.3, 1.2) |
| Cardiac disorders | 2 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.5) |
| Acute myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| General disorders and administration site conditions | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Death | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Infections and infestations | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Musculoskeletal and connective tissue disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Arthralgia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Uterine cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nervous system disorders | 2 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.5) |
| Cerebral haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Syncope | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Negative pressure pulmonary oedema | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from unblinding date to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (13:12)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_life_bnt_ol_saf

## 14.92. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2496, TE[b]=7.5) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 5 | 0.2 (0.1, 0.5) | 0.6 | (0.2, 1.5) |
| Cardiac disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 0.9) |
| Acute myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Musculoskeletal and connective tissue disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Arthralgia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Nervous system disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Cerebral haemorrhage | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Negative pressure pulmonary oedema | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from unblinding date to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_life_age_bnt_saf

## 14.93. Incidence Rates of at Least 1 Life-Threatening Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1993, TE[b]=6.5) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 4 | 0.2 (0.1, 0.5) | 0.6 | (0.2, 1.6) |
| General disorders and administration site conditions | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Death | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Infections and infestations | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Infection | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Uterine cancer | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Nervous system disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Syncope | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from unblinding date to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_life_age_bnt_saf

## 14.94. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) |
|---|---|
| Adverse Event | BNT162b2 (30 µg) (N[a]=2770) n[b] (%) |
| Any adverse event | 815 (29.4) |
| Related[c] | 747 (27.0) |
| Severe | 31 (1.1) |
| Life-threatening | 4 (0.1) |
| Any serious adverse event | 28 (1.0) |
| Related[c] | 2 (0.1) |
| Severe | 16 (0.6) |
| Life-threatening | 4 (0.1) |
| Any nonserious adverse event | 801 (28.9) |
| Related[c] | 746 (26.9) |
| Severe | 16 (0.6) |
| Life-threatening | 0 |
| Any adverse event leading to withdrawal | 0 |
| Related[c] | 0 |
| Severe | 0 |
| Life-threatening | 0 |
| Death | 0 |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (09:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s091_al_6m_3k_age_saf

## 14.95. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) |
|---|---|
| Adverse Event | BNT162b2 (30 µg) (N[a]=2230) n[b] (%) |
| Any adverse event | 551 (24.7) |
| Related[c] | 452 (20.3) |
| Severe | 38 (1.7) |
| Life-threatening | 6 (0.3) |
| Any serious adverse event | 39 (1.7) |
| Related[c] | 1 (0.0) |
| Severe | 22 (1.0) |
| Life-threatening | 6 (0.3) |
| Any nonserious adverse event | 530 (23.8) |
| Related[c] | 451 (20.2) |
| Severe | 22 (1.0) |
| Life-threatening | 0 |
| Any adverse event leading to withdrawal | 1 (0.0) |
| Related[c] | 0 |
| Severe | 0 |
| Life-threatening | 1 (0.0) |
| Death | 1 (0.0) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any adverse event," n = number of participants reporting at least 1 occurrence of any adverse event.
c. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (09:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s091_al_6m_3k_age_saf

## 14.96. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5000) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Any event | 1366 (27.3) | (26.1, 28.6) |
| Blood and lymphatic system disorders | 143 (2.9) | (2.4, 3.4) |
| Lymphadenopathy | 134 (2.7) | (2.3, 3.2) |
| Lymph node pain | 4 (0.1) | (0.0, 0.2) |
| Lymphadenitis | 2 (0.0) | (0.0, 0.1) |
| Anaemia | 1 (0.0) | (0.0, 0.1) |
| Iron deficiency anaemia | 1 (0.0) | (0.0, 0.1) |
| Leukocytosis | 1 (0.0) | (0.0, 0.1) |
| Lymphocytosis | 1 (0.0) | (0.0, 0.1) |
| Lymphopenia | 1 (0.0) | (0.0, 0.1) |
| Neutropenia | 1 (0.0) | (0.0, 0.1) |
| Sickle cell anaemia with crisis | 1 (0.0) | (0.0, 0.1) |
| Thrombocytopenia | 1 (0.0) | (0.0, 0.1) |
| Cardiac disorders | 16 (0.3) | (0.2, 0.5) |
| Atrial fibrillation | 5 (0.1) | (0.0, 0.2) |
| Palpitations | 4 (0.1) | (0.0, 0.2) |
| Acute myocardial infarction | 3 (0.1) | (0.0, 0.2) |
| Tachycardia | 3 (0.1) | (0.0, 0.2) |
| Cardiac failure | 1 (0.0) | (0.0, 0.1) |
| Myocardial infarction | 1 (0.0) | (0.0, 0.1) |
| Supraventricular tachycardia | 1 (0.0) | (0.0, 0.1) |
| Congenital, familial and genetic disorders | 1 (0.0) | (0.0, 0.1) |
| Thalassaemia beta | 1 (0.0) | (0.0, 0.1) |
| Ear and labyrinth disorders | 4 (0.1) | (0.0, 0.2) |
| Ear pain | 2 (0.0) | (0.0, 0.1) |
| Vertigo | 2 (0.0) | (0.0, 0.1) |
| Endocrine disorders | 3 (0.1) | (0.0, 0.2) |
| Hypothyroidism | 2 (0.0) | (0.0, 0.1) |
| Goitre | 1 (0.0) | (0.0, 0.1) |
| Thyroid mass | 1 (0.0) | (0.0, 0.1) |
| Eye disorders | 11 (0.2) | (0.1, 0.4) |
| Photophobia | 2 (0.0) | (0.0, 0.1) |
| Cataract | 1 (0.0) | (0.0, 0.1) |
| Chalazion | 1 (0.0) | (0.0, 0.1) |
| Diplopia | 1 (0.0) | (0.0, 0.1) |

## 14.96. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5000)<br>n[b] (%) | <br><br><br>(95% CI[c]) |
|---|---|---|
| Dry age-related macular degeneration | 1 (0.0) | (0.0, 0.1) |
| Eye pain | 1 (0.0) | (0.0, 0.1) |
| Eyelid ptosis | 1 (0.0) | (0.0, 0.1) |
| Glaucoma | 1 (0.0) | (0.0, 0.1) |
| Keratitis | 1 (0.0) | (0.0, 0.1) |
| Macular degeneration | 1 (0.0) | (0.0, 0.1) |
| Ocular hyperaemia | 1 (0.0) | (0.0, 0.1) |
| Vitreous detachment | 1 (0.0) | (0.0, 0.1) |
| Gastrointestinal disorders | 99 (2.0) | (1.6, 2.4) |
| Nausea | 51 (1.0) | (0.8, 1.3) |
| Diarrhoea | 26 (0.5) | (0.3, 0.8) |
| Vomiting | 12 (0.2) | (0.1, 0.4) |
| Dyspepsia | 3 (0.1) | (0.0, 0.2) |
| Gastrooesophageal reflux disease | 3 (0.1) | (0.0, 0.2) |
| Abdominal pain | 2 (0.0) | (0.0, 0.1) |
| Abdominal pain upper | 2 (0.0) | (0.0, 0.1) |
| Constipation | 2 (0.0) | (0.0, 0.1) |
| Aphthous ulcer | 1 (0.0) | (0.0, 0.1) |
| Colitis | 1 (0.0) | (0.0, 0.1) |
| Dental caries | 1 (0.0) | (0.0, 0.1) |
| Diverticulum | 1 (0.0) | (0.0, 0.1) |
| Dry mouth | 1 (0.0) | (0.0, 0.1) |
| Gastric fistula | 1 (0.0) | (0.0, 0.1) |
| Gastritis | 1 (0.0) | (0.0, 0.1) |
| Hiatus hernia | 1 (0.0) | (0.0, 0.1) |
| Hypoaesthesia teeth | 1 (0.0) | (0.0, 0.1) |
| Inguinal hernia | 1 (0.0) | (0.0, 0.1) |
| Intestinal perforation | 1 (0.0) | (0.0, 0.1) |
| Lower gastrointestinal haemorrhage | 1 (0.0) | (0.0, 0.1) |
| Oesophageal ulcer | 1 (0.0) | (0.0, 0.1) |
| Pancreatic pseudocyst | 1 (0.0) | (0.0, 0.1) |
| Pancreatitis acute | 1 (0.0) | (0.0, 0.1) |
| Small intestinal obstruction | 1 (0.0) | (0.0, 0.1) |
| General disorders and administration site conditions | 1080 (21.6) | (20.5, 22.8) |
| Injection site pain | 653 (13.1) | (12.1, 14.0) |
| Fatigue | 371 (7.4) | (6.7, 8.2) |

## 14.96. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5000) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Pyrexia | 251 (5.0) | (4.4, 5.7) |
| Chills | 236 (4.7) | (4.1, 5.3) |
| Pain | 137 (2.7) | (2.3, 3.2) |
| Malaise | 35 (0.7) | (0.5, 1.0) |
| Injection site erythema | 21 (0.4) | (0.3, 0.6) |
| Injection site swelling | 21 (0.4) | (0.3, 0.6) |
| Axillary pain | 13 (0.3) | (0.1, 0.4) |
| Asthenia | 9 (0.2) | (0.1, 0.3) |
| Injection site reaction | 5 (0.1) | (0.0, 0.2) |
| Feeling hot | 4 (0.1) | (0.0, 0.2) |
| Injection site pruritus | 4 (0.1) | (0.0, 0.2) |
| Swelling | 4 (0.1) | (0.0, 0.2) |
| Injection site bruising | 3 (0.1) | (0.0, 0.2) |
| Injection site inflammation | 3 (0.1) | (0.0, 0.2) |
| Injection site oedema | 3 (0.1) | (0.0, 0.2) |
| Peripheral swelling | 3 (0.1) | (0.0, 0.2) |
| Chest discomfort | 2 (0.0) | (0.0, 0.1) |
| Chest pain | 2 (0.0) | (0.0, 0.1) |
| Feeling abnormal | 2 (0.0) | (0.0, 0.1) |
| Injection site induration | 2 (0.0) | (0.0, 0.1) |
| Vaccination site pain | 2 (0.0) | (0.0, 0.1) |
| Cyst | 1 (0.0) | (0.0, 0.1) |
| Death | 1 (0.0) | (0.0, 0.1) |
| Drug withdrawal syndrome | 1 (0.0) | (0.0, 0.1) |
| Injection site discomfort | 1 (0.0) | (0.0, 0.1) |
| Injection site hypoaesthesia | 1 (0.0) | (0.0, 0.1) |
| Injection site irritation | 1 (0.0) | (0.0, 0.1) |
| Injection site paraesthesia | 1 (0.0) | (0.0, 0.1) |
| Injection site rash | 1 (0.0) | (0.0, 0.1) |
| Injection site vesicles | 1 (0.0) | (0.0, 0.1) |
| Injection site warmth | 1 (0.0) | (0.0, 0.1) |
| Injury associated with device | 1 (0.0) | (0.0, 0.1) |
| Non-cardiac chest pain | 1 (0.0) | (0.0, 0.1) |
| Sluggishness | 1 (0.0) | (0.0, 0.1) |
| Vaccination site rash | 1 (0.0) | (0.0, 0.1) |
| Hepatobiliary disorders | 4 (0.1) | (0.0, 0.2) |

## 14.96. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5000)<br>n[b] (%) | <br><br><br>(95% CI[c]) |
|---|---|---|
| Cholelithiasis | 3 (0.1) | (0.0, 0.2) |
| Bile duct stone | 1 (0.0) | (0.0, 0.1) |
| Immune system disorders | 1 (0.0) | (0.0, 0.1) |
| Food allergy | 1 (0.0) | (0.0, 0.1) |
| Infections and infestations | 46 (0.9) | (0.7, 1.2) |
| Cellulitis | 6 (0.1) | (0.0, 0.3) |
| Urinary tract infection | 4 (0.1) | (0.0, 0.2) |
| Acute sinusitis | 3 (0.1) | (0.0, 0.2) |
| Appendicitis | 3 (0.1) | (0.0, 0.2) |
| Herpes zoster | 3 (0.1) | (0.0, 0.2) |
| Appendicitis perforated | 2 (0.0) | (0.0, 0.1) |
| Cystitis | 2 (0.0) | (0.0, 0.1) |
| Ear infection | 2 (0.0) | (0.0, 0.1) |
| Hordeolum | 2 (0.0) | (0.0, 0.1) |
| Onychomycosis | 2 (0.0) | (0.0, 0.1) |
| Peritonitis | 2 (0.0) | (0.0, 0.1) |
| Tooth infection | 2 (0.0) | (0.0, 0.1) |
| Abdominal sepsis | 1 (0.0) | (0.0, 0.1) |
| Abscess | 1 (0.0) | (0.0, 0.1) |
| Adenoiditis | 1 (0.0) | (0.0, 0.1) |
| Anal fistula infection | 1 (0.0) | (0.0, 0.1) |
| Cholangitis infective | 1 (0.0) | (0.0, 0.1) |
| Conjunctivitis | 1 (0.0) | (0.0, 0.1) |
| Device related infection | 1 (0.0) | (0.0, 0.1) |
| Diverticulitis | 1 (0.0) | (0.0, 0.1) |
| Gastroenteritis | 1 (0.0) | (0.0, 0.1) |
| Infected dermal cyst | 1 (0.0) | (0.0, 0.1) |
| Latent tuberculosis | 1 (0.0) | (0.0, 0.1) |
| Liver abscess | 1 (0.0) | (0.0, 0.1) |
| Lyme disease | 1 (0.0) | (0.0, 0.1) |
| Oral herpes | 1 (0.0) | (0.0, 0.1) |
| Osteomyelitis | 1 (0.0) | (0.0, 0.1) |
| Otitis externa | 1 (0.0) | (0.0, 0.1) |
| Otitis media | 1 (0.0) | (0.0, 0.1) |
| Otitis media acute | 1 (0.0) | (0.0, 0.1) |
| Salmonellosis | 1 (0.0) | (0.0, 0.1) |

## 14.96. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5000) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Septic shock | 1 (0.0) | (0.0, 0.1) |
| Sinusitis | 1 (0.0) | (0.0, 0.1) |
| Varicella zoster virus infection | 1 (0.0) | (0.0, 0.1) |
| Vestibular neuronitis | 1 (0.0) | (0.0, 0.1) |
| Injury, poisoning and procedural complications | 31 (0.6) | (0.4, 0.9) |
| Fall | 5 (0.1) | (0.0, 0.2) |
| Skin laceration | 3 (0.1) | (0.0, 0.2) |
| Arthropod sting | 2 (0.0) | (0.0, 0.1) |
| Craniocerebral injury | 2 (0.0) | (0.0, 0.1) |
| Humerus fracture | 2 (0.0) | (0.0, 0.1) |
| Meniscus injury | 2 (0.0) | (0.0, 0.1) |
| Procedural pain | 2 (0.0) | (0.0, 0.1) |
| Road traffic accident | 2 (0.0) | (0.0, 0.1) |
| Acetabulum fracture | 1 (0.0) | (0.0, 0.1) |
| Arthropod bite | 1 (0.0) | (0.0, 0.1) |
| Bone contusion | 1 (0.0) | (0.0, 0.1) |
| Burns third degree | 1 (0.0) | (0.0, 0.1) |
| Cartilage injury | 1 (0.0) | (0.0, 0.1) |
| Clavicle fracture | 1 (0.0) | (0.0, 0.1) |
| Concussion | 1 (0.0) | (0.0, 0.1) |
| Exposure during pregnancy | 1 (0.0) | (0.0, 0.1) |
| Joint injury | 1 (0.0) | (0.0, 0.1) |
| Ligament rupture | 1 (0.0) | (0.0, 0.1) |
| Ligament sprain | 1 (0.0) | (0.0, 0.1) |
| Limb crushing injury | 1 (0.0) | (0.0, 0.1) |
| Limb injury | 1 (0.0) | (0.0, 0.1) |
| Muscle strain | 1 (0.0) | (0.0, 0.1) |
| Pelvic fracture | 1 (0.0) | (0.0, 0.1) |
| Periorbital haemorrhage | 1 (0.0) | (0.0, 0.1) |
| Post procedural haemorrhage | 1 (0.0) | (0.0, 0.1) |
| Procedural nausea | 1 (0.0) | (0.0, 0.1) |
| Rib fracture | 1 (0.0) | (0.0, 0.1) |
| Stoma complication | 1 (0.0) | (0.0, 0.1) |
| Subdural haematoma | 1 (0.0) | (0.0, 0.1) |
| Wrist fracture | 1 (0.0) | (0.0, 0.1) |
| Investigations | 36 (0.7) | (0.5, 1.0) |

## 14.96. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5000)<br>n[b] (%) | <br><br><br>(95% CI[c]) |
|---|---|---|
| Body temperature increased | 30 (0.6) | (0.4, 0.9) |
| Hepatic enzyme increased | 2 (0.0) | (0.0, 0.1) |
| Blood cholesterol increased | 1 (0.0) | (0.0, 0.1) |
| Blood pressure increased | 1 (0.0) | (0.0, 0.1) |
| Inflammatory marker increased | 1 (0.0) | (0.0, 0.1) |
| Lipase increased | 1 (0.0) | (0.0, 0.1) |
| Respiratory rate increased | 1 (0.0) | (0.0, 0.1) |
| Metabolism and nutrition disorders | 22 (0.4) | (0.3, 0.7) |
| Decreased appetite | 10 (0.2) | (0.1, 0.4) |
| Hypercholesterolaemia | 4 (0.1) | (0.0, 0.2) |
| Type 2 diabetes mellitus | 3 (0.1) | (0.0, 0.2) |
| Dehydration | 1 (0.0) | (0.0, 0.1) |
| Glucose tolerance impaired | 1 (0.0) | (0.0, 0.1) |
| Hypervolaemia | 1 (0.0) | (0.0, 0.1) |
| Hypokalaemia | 1 (0.0) | (0.0, 0.1) |
| Hyponatraemia | 1 (0.0) | (0.0, 0.1) |
| Musculoskeletal and connective tissue disorders | 358 (7.2) | (6.5, 7.9) |
| Myalgia | 240 (4.8) | (4.2, 5.4) |
| Pain in extremity | 57 (1.1) | (0.9, 1.5) |
| Arthralgia | 43 (0.9) | (0.6, 1.2) |
| Neck pain | 10 (0.2) | (0.1, 0.4) |
| Back pain | 9 (0.2) | (0.1, 0.3) |
| Synovial cyst | 4 (0.1) | (0.0, 0.2) |
| Joint swelling | 2 (0.0) | (0.0, 0.1) |
| Muscular weakness | 2 (0.0) | (0.0, 0.1) |
| Musculoskeletal chest pain | 2 (0.0) | (0.0, 0.1) |
| Musculoskeletal stiffness | 2 (0.0) | (0.0, 0.1) |
| Osteoarthritis | 2 (0.0) | (0.0, 0.1) |
| Bone cyst | 1 (0.0) | (0.0, 0.1) |
| Bone pain | 1 (0.0) | (0.0, 0.1) |
| Foot deformity | 1 (0.0) | (0.0, 0.1) |
| Intervertebral disc protrusion | 1 (0.0) | (0.0, 0.1) |
| Intervertebral disc space narrowing | 1 (0.0) | (0.0, 0.1) |
| Joint effusion | 1 (0.0) | (0.0, 0.1) |
| Joint stiffness | 1 (0.0) | (0.0, 0.1) |
| Muscle swelling | 1 (0.0) | (0.0, 0.1) |

## 14.96. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5000)<br>n[b] (%) | <br><br><br>(95% CI[c]) |
|---|---|---|
| Musculoskeletal pain | 1 (0.0) | (0.0, 0.1) |
| Osteoporosis | 1 (0.0) | (0.0, 0.1) |
| Pain in jaw | 1 (0.0) | (0.0, 0.1) |
| Rotator cuff syndrome | 1 (0.0) | (0.0, 0.1) |
| Scoliosis | 1 (0.0) | (0.0, 0.1) |
| Spondylolisthesis | 1 (0.0) | (0.0, 0.1) |
| Tendonitis | 1 (0.0) | (0.0, 0.1) |
| Trigger finger | 1 (0.0) | (0.0, 0.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 25 (0.5) | (0.3, 0.7) |
| Basal cell carcinoma | 3 (0.1) | (0.0, 0.2) |
| Breast cancer | 2 (0.0) | (0.0, 0.1) |
| Invasive ductal breast carcinoma | 2 (0.0) | (0.0, 0.1) |
| Malignant melanoma | 2 (0.0) | (0.0, 0.1) |
| Prostate cancer | 2 (0.0) | (0.0, 0.1) |
| Acute lymphocytic leukaemia | 1 (0.0) | (0.0, 0.1) |
| Brain neoplasm | 1 (0.0) | (0.0, 0.1) |
| Focal nodular hyperplasia | 1 (0.0) | (0.0, 0.1) |
| Follicular lymphoma | 1 (0.0) | (0.0, 0.1) |
| Granular cell tumour | 1 (0.0) | (0.0, 0.1) |
| Lipoma | 1 (0.0) | (0.0, 0.1) |
| Meningioma | 1 (0.0) | (0.0, 0.1) |
| Nervous system neoplasm | 1 (0.0) | (0.0, 0.1) |
| Ovarian cancer | 1 (0.0) | (0.0, 0.1) |
| Renal cell carcinoma | 1 (0.0) | (0.0, 0.1) |
| Skin cancer | 1 (0.0) | (0.0, 0.1) |
| Squamous cell carcinoma | 1 (0.0) | (0.0, 0.1) |
| Uterine cancer | 1 (0.0) | (0.0, 0.1) |
| Uterine leiomyoma | 1 (0.0) | (0.0, 0.1) |
| Nervous system disorders | 299 (6.0) | (5.3, 6.7) |
| Headache | 257 (5.1) | (4.5, 5.8) |
| Lethargy | 12 (0.2) | (0.1, 0.4) |
| Dizziness | 9 (0.2) | (0.1, 0.3) |
| Syncope | 5 (0.1) | (0.0, 0.2) |
| Migraine | 4 (0.1) | (0.0, 0.2) |
| Hypoaesthesia | 3 (0.1) | (0.0, 0.2) |
| Cerebrovascular accident | 2 (0.0) | (0.0, 0.1) |

## 14.96. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5000)<br>n[b] (%) | <br><br><br>(95% CI[c]) |
|---|---|---|
| Hyperaesthesia | 2 (0.0) | (0.0, 0.1) |
| Paraesthesia | 2 (0.0) | (0.0, 0.1) |
| Altered state of consciousness | 1 (0.0) | (0.0, 0.1) |
| Carpal tunnel syndrome | 1 (0.0) | (0.0, 0.1) |
| Cerebral haemorrhage | 1 (0.0) | (0.0, 0.1) |
| Dysgeusia | 1 (0.0) | (0.0, 0.1) |
| Intracranial aneurysm | 1 (0.0) | (0.0, 0.1) |
| Migraine with aura | 1 (0.0) | (0.0, 0.1) |
| Neuralgic amyotrophy | 1 (0.0) | (0.0, 0.1) |
| Parosmia | 1 (0.0) | (0.0, 0.1) |
| Presyncope | 1 (0.0) | (0.0, 0.1) |
| Sciatica | 1 (0.0) | (0.0, 0.1) |
| Seizure | 1 (0.0) | (0.0, 0.1) |
| Somnolence | 1 (0.0) | (0.0, 0.1) |
| Taste disorder | 1 (0.0) | (0.0, 0.1) |
| Tension headache | 1 (0.0) | (0.0, 0.1) |
| Toxic encephalopathy | 1 (0.0) | (0.0, 0.1) |
| Tremor | 1 (0.0) | (0.0, 0.1) |
| Pregnancy, puerperium and perinatal conditions | 4 (0.1) | (0.0, 0.2) |
| Abortion spontaneous | 2 (0.0) | (0.0, 0.1) |
| Pregnancy | 2 (0.0) | (0.0, 0.1) |
| Psychiatric disorders | 18 (0.4) | (0.2, 0.6) |
| Depression | 5 (0.1) | (0.0, 0.2) |
| Anxiety | 3 (0.1) | (0.0, 0.2) |
| Attention deficit hyperactivity disorder | 3 (0.1) | (0.0, 0.2) |
| Insomnia | 2 (0.0) | (0.0, 0.1) |
| Abnormal dreams | 1 (0.0) | (0.0, 0.1) |
| Adjustment disorder with mixed anxiety and depressed mood | 1 (0.0) | (0.0, 0.1) |
| Generalised anxiety disorder | 1 (0.0) | (0.0, 0.1) |
| Mood altered | 1 (0.0) | (0.0, 0.1) |
| Poor quality sleep | 1 (0.0) | (0.0, 0.1) |
| Stress | 1 (0.0) | (0.0, 0.1) |
| Suicidal ideation | 1 (0.0) | (0.0, 0.1) |
| Renal and urinary disorders | 13 (0.3) | (0.1, 0.4) |
| Nephrolithiasis | 4 (0.1) | (0.0, 0.2) |
| Renal cyst | 2 (0.0) | (0.0, 0.1) |

## 14.96. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5000)<br>n[b] (%) | <br><br><br>(95% CI[c]) |
|---|---|---|
| Urinary incontinence | 2 (0.0) | (0.0, 0.1) |
| Dysuria | 1 (0.0) | (0.0, 0.1) |
| End stage renal disease | 1 (0.0) | (0.0, 0.1) |
| Haematuria | 1 (0.0) | (0.0, 0.1) |
| Renal colic | 1 (0.0) | (0.0, 0.1) |
| Stress urinary incontinence | 1 (0.0) | (0.0, 0.1) |
| Reproductive system and breast disorders | 12 (0.2) | (0.1, 0.4) |
| Atrophic vulvovaginitis | 2 (0.0) | (0.0, 0.1) |
| Menstruation irregular | 2 (0.0) | (0.0, 0.1) |
| Ovarian cyst | 2 (0.0) | (0.0, 0.1) |
| Breast mass | 1 (0.0) | (0.0, 0.1) |
| Breast pain | 1 (0.0) | (0.0, 0.1) |
| Heavy menstrual bleeding | 1 (0.0) | (0.0, 0.1) |
| Intermenstrual bleeding | 1 (0.0) | (0.0, 0.1) |
| Menopausal symptoms | 1 (0.0) | (0.0, 0.1) |
| Prostatitis | 1 (0.0) | (0.0, 0.1) |
| Scrotal disorder | 1 (0.0) | (0.0, 0.1) |
| Respiratory, thoracic and mediastinal disorders | 17 (0.3) | (0.2, 0.5) |
| Asthma | 3 (0.1) | (0.0, 0.2) |
| Epistaxis | 3 (0.1) | (0.0, 0.2) |
| Nasal congestion | 3 (0.1) | (0.0, 0.2) |
| Rhinorrhoea | 3 (0.1) | (0.0, 0.2) |
| Sinus congestion | 2 (0.0) | (0.0, 0.1) |
| Acute respiratory failure | 1 (0.0) | (0.0, 0.1) |
| Dry throat | 1 (0.0) | (0.0, 0.1) |
| Pharyngeal swelling | 1 (0.0) | (0.0, 0.1) |
| Throat tightness | 1 (0.0) | (0.0, 0.1) |
| Upper-airway cough syndrome | 1 (0.0) | (0.0, 0.1) |
| Skin and subcutaneous tissue disorders | 26 (0.5) | (0.3, 0.8) |
| Hyperhidrosis | 5 (0.1) | (0.0, 0.2) |
| Night sweats | 5 (0.1) | (0.0, 0.2) |
| Rash | 4 (0.1) | (0.0, 0.2) |
| Pruritus | 3 (0.1) | (0.0, 0.2) |
| Urticaria | 2 (0.0) | (0.0, 0.1) |
| Alopecia | 1 (0.0) | (0.0, 0.1) |
| Alopecia areata | 1 (0.0) | (0.0, 0.1) |

## 14.96. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=5000)<br>n[b] (%) | <br><br><br>(95% CI[c]) |
|---|---|---|
| Dermatitis contact | 1 (0.0) | (0.0, 0.1) |
| Dry skin | 1 (0.0) | (0.0, 0.1) |
| Erythema | 1 (0.0) | (0.0, 0.1) |
| Psoriasis | 1 (0.0) | (0.0, 0.1) |
| Rash erythematous | 1 (0.0) | (0.0, 0.1) |
| Rash maculo-papular | 1 (0.0) | (0.0, 0.1) |
| Xanthoma | 1 (0.0) | (0.0, 0.1) |
| Surgical and medical procedures | 2 (0.0) | (0.0, 0.1) |
| Bunion operation | 1 (0.0) | (0.0, 0.1) |
| Gastrectomy | 1 (0.0) | (0.0, 0.1) |
| Vascular disorders | 9 (0.2) | (0.1, 0.3) |
| Hypertension | 6 (0.1) | (0.0, 0.3) |
| Hot flush | 2 (0.0) | (0.0, 0.1) |
| Haematoma | 1 (0.0) | (0.0, 0.1) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (13:12)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_all_6m_3k_saf

## 14.97. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2770)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Any event | 815 (29.4) | (27.7, 31.2) |
| Blood and lymphatic system disorders | 119 (4.3) | (3.6, 5.1) |
| Lymphadenopathy | 111 (4.0) | (3.3, 4.8) |
| Lymph node pain | 4 (0.1) | (0.0, 0.4) |
| Lymphadenitis | 2 (0.1) | (0.0, 0.3) |
| Anaemia | 0 | (0.0, 0.1) |
| Iron deficiency anaemia | 1 (0.0) | (0.0, 0.2) |
| Leukocytosis | 1 (0.0) | (0.0, 0.2) |
| Lymphocytosis | 1 (0.0) | (0.0, 0.2) |
| Lymphopenia | 1 (0.0) | (0.0, 0.2) |
| Neutropenia | 1 (0.0) | (0.0, 0.2) |
| Sickle cell anaemia with crisis | 1 (0.0) | (0.0, 0.2) |
| Thrombocytopenia | 1 (0.0) | (0.0, 0.2) |
| Cardiac disorders | 8 (0.3) | (0.1, 0.6) |
| Atrial fibrillation | 1 (0.0) | (0.0, 0.2) |
| Palpitations | 3 (0.1) | (0.0, 0.3) |
| Acute myocardial infarction | 1 (0.0) | (0.0, 0.2) |
| Tachycardia | 2 (0.1) | (0.0, 0.3) |
| Cardiac failure | 0 | (0.0, 0.1) |
| Myocardial infarction | 0 | (0.0, 0.1) |
| Supraventricular tachycardia | 1 (0.0) | (0.0, 0.2) |
| Congenital, familial and genetic disorders | 1 (0.0) | (0.0, 0.2) |
| Thalassaemia beta | 1 (0.0) | (0.0, 0.2) |
| Ear and labyrinth disorders | 3 (0.1) | (0.0, 0.3) |
| Ear pain | 1 (0.0) | (0.0, 0.2) |
| Vertigo | 2 (0.1) | (0.0, 0.3) |
| Endocrine disorders | 1 (0.0) | (0.0, 0.2) |
| Hypothyroidism | 1 (0.0) | (0.0, 0.2) |
| Goitre | 1 (0.0) | (0.0, 0.2) |
| Thyroid mass | 0 | (0.0, 0.1) |
| Eye disorders | 4 (0.1) | (0.0, 0.4) |
| Photophobia | 2 (0.1) | (0.0, 0.3) |
| Cataract | 0 | (0.0, 0.1) |

**14.97. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2770)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Chalazion | 0 | (0.0, 0.1) |
| Diplopia | 1 (0.0) | (0.0, 0.2) |
| Dry age-related macular degeneration | 0 | (0.0, 0.1) |
| Eye pain | 1 (0.0) | (0.0, 0.2) |
| Eyelid ptosis | 0 | (0.0, 0.1) |
| Glaucoma | 0 | (0.0, 0.1) |
| Keratitis | 0 | (0.0, 0.1) |
| Macular degeneration | 0 | (0.0, 0.1) |
| Ocular hyperaemia | 1 (0.0) | (0.0, 0.2) |
| Vitreous detachment | 0 | (0.0, 0.1) |
| Gastrointestinal disorders | 56 (2.0) | (1.5, 2.6) |
| Nausea | 24 (0.9) | (0.6, 1.3) |
| Diarrhoea | 18 (0.6) | (0.4, 1.0) |
| Vomiting | 7 (0.3) | (0.1, 0.5) |
| Dyspepsia | 2 (0.1) | (0.0, 0.3) |
| Gastrooesophageal reflux disease | 3 (0.1) | (0.0, 0.3) |
| Abdominal pain | 2 (0.1) | (0.0, 0.3) |
| Abdominal pain upper | 1 (0.0) | (0.0, 0.2) |
| Constipation | 2 (0.1) | (0.0, 0.3) |
| Aphthous ulcer | 0 | (0.0, 0.1) |
| Colitis | 0 | (0.0, 0.1) |
| Dental caries | 1 (0.0) | (0.0, 0.2) |
| Diverticulum | 0 | (0.0, 0.1) |
| Dry mouth | 1 (0.0) | (0.0, 0.2) |
| Gastric fistula | 1 (0.0) | (0.0, 0.2) |
| Gastritis | 0 | (0.0, 0.1) |
| Hiatus hernia | 0 | (0.0, 0.1) |
| Hypoaesthesia teeth | 1 (0.0) | (0.0, 0.2) |
| Inguinal hernia | 0 | (0.0, 0.1) |
| Intestinal perforation | 1 (0.0) | (0.0, 0.2) |
| Lower gastrointestinal haemorrhage | 0 | (0.0, 0.1) |
| Oesophageal ulcer | 0 | (0.0, 0.1) |
| Pancreatic pseudocyst | 1 (0.0) | (0.0, 0.2) |
| Pancreatitis acute | 1 (0.0) | (0.0, 0.2) |
| Small intestinal obstruction | 0 | (0.0, 0.1) |

## 14.97. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2770)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| General disorders and administration site conditions | 668 (24.1) | (22.5, 25.8) |
| Injection site pain | 413 (14.9) | (13.6, 16.3) |
| Fatigue | 211 (7.6) | (6.7, 8.7) |
| Pyrexia | 158 (5.7) | (4.9, 6.6) |
| Chills | 151 (5.5) | (4.6, 6.4) |
| Pain | 82 (3.0) | (2.4, 3.7) |
| Malaise | 25 (0.9) | (0.6, 1.3) |
| Injection site erythema | 9 (0.3) | (0.1, 0.6) |
| Injection site swelling | 11 (0.4) | (0.2, 0.7) |
| Axillary pain | 10 (0.4) | (0.2, 0.7) |
| Asthenia | 5 (0.2) | (0.1, 0.4) |
| Injection site reaction | 4 (0.1) | (0.0, 0.4) |
| Feeling hot | 4 (0.1) | (0.0, 0.4) |
| Injection site pruritus | 1 (0.0) | (0.0, 0.2) |
| Swelling | 2 (0.1) | (0.0, 0.3) |
| Injection site bruising | 2 (0.1) | (0.0, 0.3) |
| Injection site inflammation | 2 (0.1) | (0.0, 0.3) |
| Injection site oedema | 2 (0.1) | (0.0, 0.3) |
| Peripheral swelling | 1 (0.0) | (0.0, 0.2) |
| Chest discomfort | 1 (0.0) | (0.0, 0.2) |
| Chest pain | 2 (0.1) | (0.0, 0.3) |
| Feeling abnormal | 2 (0.1) | (0.0, 0.3) |
| Injection site induration | 2 (0.1) | (0.0, 0.3) |
| Vaccination site pain | 2 (0.1) | (0.0, 0.3) |
| Cyst | 0 | (0.0, 0.1) |
| Death | 0 | (0.0, 0.1) |
| Drug withdrawal syndrome | 1 (0.0) | (0.0, 0.2) |
| Injection site discomfort | 1 (0.0) | (0.0, 0.2) |
| Injection site hypoaesthesia | 0 | (0.0, 0.1) |
| Injection site irritation | 0 | (0.0, 0.1) |
| Injection site paraesthesia | 1 (0.0) | (0.0, 0.2) |
| Injection site rash | 0 | (0.0, 0.1) |
| Injection site vesicles | 0 | (0.0, 0.1) |
| Injection site warmth | 0 | (0.0, 0.1) |
| Injury associated with device | 1 (0.0) | (0.0, 0.2) |
| Non-cardiac chest pain | 1 (0.0) | (0.0, 0.2) |

**14.97. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2770)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Sluggishness | 1 (0.0) | (0.0, 0.2) |
| Vaccination site rash | 1 (0.0) | (0.0, 0.2) |
| Hepatobiliary disorders | 4 (0.1) | (0.0, 0.4) |
| Cholelithiasis | 3 (0.1) | (0.0, 0.3) |
| Bile duct stone | 1 (0.0) | (0.0, 0.2) |
| Immune system disorders | 0 | (0.0, 0.1) |
| Food allergy | 0 | (0.0, 0.1) |
| Infections and infestations | 24 (0.9) | (0.6, 1.3) |
| Cellulitis | 0 | (0.0, 0.1) |
| Urinary tract infection | 3 (0.1) | (0.0, 0.3) |
| Acute sinusitis | 1 (0.0) | (0.0, 0.2) |
| Appendicitis | 2 (0.1) | (0.0, 0.3) |
| Herpes zoster | 3 (0.1) | (0.0, 0.3) |
| Appendicitis perforated | 0 | (0.0, 0.1) |
| Cystitis | 0 | (0.0, 0.1) |
| Ear infection | 1 (0.0) | (0.0, 0.2) |
| Hordeolum | 2 (0.1) | (0.0, 0.3) |
| Onychomycosis | 1 (0.0) | (0.0, 0.2) |
| Peritonitis | 1 (0.0) | (0.0, 0.2) |
| Tooth infection | 1 (0.0) | (0.0, 0.2) |
| Abdominal sepsis | 1 (0.0) | (0.0, 0.2) |
| Abscess | 0 | (0.0, 0.1) |
| Adenoiditis | 1 (0.0) | (0.0, 0.2) |
| Anal fistula infection | 1 (0.0) | (0.0, 0.2) |
| Cholangitis infective | 1 (0.0) | (0.0, 0.2) |
| Conjunctivitis | 1 (0.0) | (0.0, 0.2) |
| Device related infection | 0 | (0.0, 0.1) |
| Diverticulitis | 0 | (0.0, 0.1) |
| Gastroenteritis | 1 (0.0) | (0.0, 0.2) |
| Infected dermal cyst | 0 | (0.0, 0.1) |
| Latent tuberculosis | 1 (0.0) | (0.0, 0.2) |
| Liver abscess | 0 | (0.0, 0.1) |
| Lyme disease | 1 (0.0) | (0.0, 0.2) |
| Oral herpes | 1 (0.0) | (0.0, 0.2) |
| Osteomyelitis | 0 | (0.0, 0.1) |

**14.97. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2770)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Otitis externa | 1 (0.0) | (0.0, 0.2) |
| Otitis media | 1 (0.0) | (0.0, 0.2) |
| Otitis media acute | 0 | (0.0, 0.1) |
| Salmonellosis | 0 | (0.0, 0.1) |
| Septic shock | 1 (0.0) | (0.0, 0.2) |
| Sinusitis | 1 (0.0) | (0.0, 0.2) |
| Varicella zoster virus infection | 0 | (0.0, 0.1) |
| Vestibular neuronitis | 0 | (0.0, 0.1) |
| Injury, poisoning and procedural complications | 14 (0.5) | (0.3, 0.8) |
| Fall | 2 (0.1) | (0.0, 0.3) |
| Skin laceration | 1 (0.0) | (0.0, 0.2) |
| Arthropod sting | 0 | (0.0, 0.1) |
| Craniocerebral injury | 0 | (0.0, 0.1) |
| Humerus fracture | 1 (0.0) | (0.0, 0.2) |
| Meniscus injury | 1 (0.0) | (0.0, 0.2) |
| Procedural pain | 2 (0.1) | (0.0, 0.3) |
| Road traffic accident | 1 (0.0) | (0.0, 0.2) |
| Acetabulum fracture | 0 | (0.0, 0.1) |
| Arthropod bite | 0 | (0.0, 0.1) |
| Bone contusion | 1 (0.0) | (0.0, 0.2) |
| Burns third degree | 0 | (0.0, 0.1) |
| Cartilage injury | 1 (0.0) | (0.0, 0.2) |
| Clavicle fracture | 0 | (0.0, 0.1) |
| Concussion | 1 (0.0) | (0.0, 0.2) |
| Exposure during pregnancy | 1 (0.0) | (0.0, 0.2) |
| Joint injury | 1 (0.0) | (0.0, 0.2) |
| Ligament rupture | 1 (0.0) | (0.0, 0.2) |
| Ligament sprain | 1 (0.0) | (0.0, 0.2) |
| Limb crushing injury | 0 | (0.0, 0.1) |
| Limb injury | 0 | (0.0, 0.1) |
| Muscle strain | 0 | (0.0, 0.1) |
| Pelvic fracture | 0 | (0.0, 0.1) |
| Periorbital haemorrhage | 0 | (0.0, 0.1) |
| Post procedural haemorrhage | 1 (0.0) | (0.0, 0.2) |
| Procedural nausea | 1 (0.0) | (0.0, 0.2) |
| Rib fracture | 0 | (0.0, 0.1) |

**14.97. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2770)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Stoma complication | 1 (0.0) | (0.0, 0.2) |
| Subdural haematoma | 0 | (0.0, 0.1) |
| Wrist fracture | 0 | (0.0, 0.1) |
| Investigations | 23 (0.8) | (0.5, 1.2) |
| Body temperature increased | 19 (0.7) | (0.4, 1.1) |
| Hepatic enzyme increased | 1 (0.0) | (0.0, 0.2) |
| Blood cholesterol increased | 1 (0.0) | (0.0, 0.2) |
| Blood pressure increased | 1 (0.0) | (0.0, 0.2) |
| Inflammatory marker increased | 1 (0.0) | (0.0, 0.2) |
| Lipase increased | 0 | (0.0, 0.1) |
| Respiratory rate increased | 1 (0.0) | (0.0, 0.2) |
| Metabolism and nutrition disorders | 7 (0.3) | (0.1, 0.5) |
| Decreased appetite | 5 (0.2) | (0.1, 0.4) |
| Hypercholesterolaemia | 0 | (0.0, 0.1) |
| Type 2 diabetes mellitus | 2 (0.1) | (0.0, 0.3) |
| Dehydration | 0 | (0.0, 0.1) |
| Glucose tolerance impaired | 0 | (0.0, 0.1) |
| Hypervolaemia | 0 | (0.0, 0.1) |
| Hypokalaemia | 0 | (0.0, 0.1) |
| Hyponatraemia | 0 | (0.0, 0.1) |
| Musculoskeletal and connective tissue disorders | 214 (7.7) | (6.8, 8.8) |
| Myalgia | 157 (5.7) | (4.8, 6.6) |
| Pain in extremity | 27 (1.0) | (0.6, 1.4) |
| Arthralgia | 23 (0.8) | (0.5, 1.2) |
| Neck pain | 5 (0.2) | (0.1, 0.4) |
| Back pain | 4 (0.1) | (0.0, 0.4) |
| Synovial cyst | 4 (0.1) | (0.0, 0.4) |
| Joint swelling | 0 | (0.0, 0.1) |
| Muscular weakness | 2 (0.1) | (0.0, 0.3) |
| Musculoskeletal chest pain | 1 (0.0) | (0.0, 0.2) |
| Musculoskeletal stiffness | 2 (0.1) | (0.0, 0.3) |
| Osteoarthritis | 1 (0.0) | (0.0, 0.2) |
| Bone cyst | 0 | (0.0, 0.1) |
| Bone pain | 1 (0.0) | (0.0, 0.2) |
| Foot deformity | 0 | (0.0, 0.1) |

**14.97. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2770)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Intervertebral disc protrusion | 0 | (0.0, 0.1) |
| Intervertebral disc space narrowing | 0 | (0.0, 0.1) |
| Joint effusion | 0 | (0.0, 0.1) |
| Joint stiffness | 0 | (0.0, 0.1) |
| Muscle swelling | 0 | (0.0, 0.1) |
| Musculoskeletal pain | 0 | (0.0, 0.1) |
| Osteoporosis | 0 | (0.0, 0.1) |
| Pain in jaw | 1 (0.0) | (0.0, 0.2) |
| Rotator cuff syndrome | 0 | (0.0, 0.1) |
| Scoliosis | 1 (0.0) | (0.0, 0.2) |
| Spondylolisthesis | 0 | (0.0, 0.1) |
| Tendonitis | 0 | (0.0, 0.1) |
| Trigger finger | 0 | (0.0, 0.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 8 (0.3) | (0.1, 0.6) |
| Basal cell carcinoma | 0 | (0.0, 0.1) |
| Breast cancer | 0 | (0.0, 0.1) |
| Invasive ductal breast carcinoma | 0 | (0.0, 0.1) |
| Malignant melanoma | 0 | (0.0, 0.1) |
| Prostate cancer | 0 | (0.0, 0.1) |
| Acute lymphocytic leukaemia | 1 (0.0) | (0.0, 0.2) |
| Brain neoplasm | 1 (0.0) | (0.0, 0.2) |
| Focal nodular hyperplasia | 1 (0.0) | (0.0, 0.2) |
| Follicular lymphoma | 0 | (0.0, 0.1) |
| Granular cell tumour | 1 (0.0) | (0.0, 0.2) |
| Lipoma | 1 (0.0) | (0.0, 0.2) |
| Meningioma | 1 (0.0) | (0.0, 0.2) |
| Nervous system neoplasm | 1 (0.0) | (0.0, 0.2) |
| Ovarian cancer | 0 | (0.0, 0.1) |
| Renal cell carcinoma | 0 | (0.0, 0.1) |
| Skin cancer | 0 | (0.0, 0.1) |
| Squamous cell carcinoma | 0 | (0.0, 0.1) |
| Uterine cancer | 0 | (0.0, 0.1) |
| Uterine leiomyoma | 1 (0.0) | (0.0, 0.2) |
| Nervous system disorders | 182 (6.6) | (5.7, 7.6) |
| Headache | 158 (5.7) | (4.9, 6.6) |

**14.97. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2770)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Lethargy | 4 (0.1) | (0.0, 0.4) |
| Dizziness | 7 (0.3) | (0.1, 0.5) |
| Syncope | 0 | (0.0, 0.1) |
| Migraine | 3 (0.1) | (0.0, 0.3) |
| Hypoaesthesia | 2 (0.1) | (0.0, 0.3) |
| Cerebrovascular accident | 0 | (0.0, 0.1) |
| Hyperaesthesia | 1 (0.0) | (0.0, 0.2) |
| Paraesthesia | 2 (0.1) | (0.0, 0.3) |
| Altered state of consciousness | 0 | (0.0, 0.1) |
| Carpal tunnel syndrome | 1 (0.0) | (0.0, 0.2) |
| Cerebral haemorrhage | 1 (0.0) | (0.0, 0.2) |
| Dysgeusia | 0 | (0.0, 0.1) |
| Intracranial aneurysm | 1 (0.0) | (0.0, 0.2) |
| Migraine with aura | 0 | (0.0, 0.1) |
| Neuralgic amyotrophy | 1 (0.0) | (0.0, 0.2) |
| Parosmia | 1 (0.0) | (0.0, 0.2) |
| Presyncope | 0 | (0.0, 0.1) |
| Sciatica | 1 (0.0) | (0.0, 0.2) |
| Seizure | 1 (0.0) | (0.0, 0.2) |
| Somnolence | 1 (0.0) | (0.0, 0.2) |
| Taste disorder | 1 (0.0) | (0.0, 0.2) |
| Tension headache | 1 (0.0) | (0.0, 0.2) |
| Toxic encephalopathy | 1 (0.0) | (0.0, 0.2) |
| Tremor | 1 (0.0) | (0.0, 0.2) |
| Pregnancy, puerperium and perinatal conditions | 4 (0.1) | (0.0, 0.4) |
| Abortion spontaneous | 2 (0.1) | (0.0, 0.3) |
| Pregnancy | 2 (0.1) | (0.0, 0.3) |
| Psychiatric disorders | 12 (0.4) | (0.2, 0.8) |
| Depression | 3 (0.1) | (0.0, 0.3) |
| Anxiety | 1 (0.0) | (0.0, 0.2) |
| Attention deficit hyperactivity disorder | 3 (0.1) | (0.0, 0.3) |
| Insomnia | 1 (0.0) | (0.0, 0.2) |
| Abnormal dreams | 1 (0.0) | (0.0, 0.2) |
| Adjustment disorder with mixed anxiety and depressed mood | 1 (0.0) | (0.0, 0.2) |
| Generalised anxiety disorder | 1 (0.0) | (0.0, 0.2) |

**14.97. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2770)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Mood altered | 1 (0.0) | (0.0, 0.2) |
| Poor quality sleep | 0 | (0.0, 0.1) |
| Stress | 1 (0.0) | (0.0, 0.2) |
| Suicidal ideation | 1 (0.0) | (0.0, 0.2) |
| Renal and urinary disorders | 2 (0.1) | (0.0, 0.3) |
| Nephrolithiasis | 2 (0.1) | (0.0, 0.3) |
| Renal cyst | 0 | (0.0, 0.1) |
| Urinary incontinence | 0 | (0.0, 0.1) |
| Dysuria | 0 | (0.0, 0.1) |
| End stage renal disease | 0 | (0.0, 0.1) |
| Haematuria | 0 | (0.0, 0.1) |
| Renal colic | 0 | (0.0, 0.1) |
| Stress urinary incontinence | 0 | (0.0, 0.1) |
| Reproductive system and breast disorders | 6 (0.2) | (0.1, 0.5) |
| Atrophic vulvovaginitis | 0 | (0.0, 0.1) |
| Menstruation irregular | 2 (0.1) | (0.0, 0.3) |
| Ovarian cyst | 2 (0.1) | (0.0, 0.3) |
| Breast mass | 0 | (0.0, 0.1) |
| Breast pain | 0 | (0.0, 0.1) |
| Heavy menstrual bleeding | 1 (0.0) | (0.0, 0.2) |
| Intermenstrual bleeding | 1 (0.0) | (0.0, 0.2) |
| Menopausal symptoms | 1 (0.0) | (0.0, 0.2) |
| Prostatitis | 0 | (0.0, 0.1) |
| Scrotal disorder | 0 | (0.0, 0.1) |
| Respiratory, thoracic and mediastinal disorders | 8 (0.3) | (0.1, 0.6) |
| Asthma | 1 (0.0) | (0.0, 0.2) |
| Epistaxis | 0 | (0.0, 0.1) |
| Nasal congestion | 1 (0.0) | (0.0, 0.2) |
| Rhinorrhoea | 2 (0.1) | (0.0, 0.3) |
| Sinus congestion | 0 | (0.0, 0.1) |
| Acute respiratory failure | 0 | (0.0, 0.1) |
| Dry throat | 1 (0.0) | (0.0, 0.2) |
| Pharyngeal swelling | 1 (0.0) | (0.0, 0.2) |
| Throat tightness | 1 (0.0) | (0.0, 0.2) |
| Upper-airway cough syndrome | 1 (0.0) | (0.0, 0.2) |

## 14.97. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=2770)<br>n[b] (%) | (95% CI[c]) |
|---|---|---|
| Skin and subcutaneous tissue disorders | 13 (0.5) | (0.3, 0.8) |
| Hyperhidrosis | 3 (0.1) | (0.0, 0.3) |
| Night sweats | 4 (0.1) | (0.0, 0.4) |
| Rash | 1 (0.0) | (0.0, 0.2) |
| Pruritus | 2 (0.1) | (0.0, 0.3) |
| Urticaria | 1 (0.0) | (0.0, 0.2) |
| Alopecia | 1 (0.0) | (0.0, 0.2) |
| Alopecia areata | 0 | (0.0, 0.1) |
| Dermatitis contact | 0 | (0.0, 0.1) |
| Dry skin | 0 | (0.0, 0.1) |
| Erythema | 1 (0.0) | (0.0, 0.2) |
| Psoriasis | 0 | (0.0, 0.1) |
| Rash erythematous | 1 (0.0) | (0.0, 0.2) |
| Rash maculo-papular | 0 | (0.0, 0.1) |
| Xanthoma | 0 | (0.0, 0.1) |
| Surgical and medical procedures | 0 | (0.0, 0.1) |
| Bunion operation | 0 | (0.0, 0.1) |
| Gastrectomy | 0 | (0.0, 0.1) |
| Vascular disorders | 4 (0.1) | (0.0, 0.4) |
| Hypertension | 2 (0.1) | (0.0, 0.3) |
| Hot flush | 2 (0.1) | (0.0, 0.3) |
| Haematoma | 0 | (0.0, 0.1) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (09:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: /nda2_ubBIA/C4591031_A_SBLA/adae_s130_all_6m_3k_age_saf

## 14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2230) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Any event | 551 (24.7) | (22.9, 26.6) |
| Blood and lymphatic system disorders | 24 (1.1) | (0.7, 1.6) |
| Lymphadenopathy | 23 (1.0) | (0.7, 1.5) |
| Lymph node pain | 0 | (0.0, 0.2) |
| Lymphadenitis | 0 | (0.0, 0.2) |
| Anaemia | 1 (0.0) | (0.0, 0.2) |
| Iron deficiency anaemia | 0 | (0.0, 0.2) |
| Leukocytosis | 0 | (0.0, 0.2) |
| Lymphocytosis | 0 | (0.0, 0.2) |
| Lymphopenia | 0 | (0.0, 0.2) |
| Neutropenia | 0 | (0.0, 0.2) |
| Sickle cell anaemia with crisis | 0 | (0.0, 0.2) |
| Thrombocytopenia | 0 | (0.0, 0.2) |
| Cardiac disorders | 8 (0.4) | (0.2, 0.7) |
| Atrial fibrillation | 4 (0.2) | (0.0, 0.5) |
| Palpitations | 1 (0.0) | (0.0, 0.2) |
| Acute myocardial infarction | 2 (0.1) | (0.0, 0.3) |
| Tachycardia | 1 (0.0) | (0.0, 0.2) |
| Cardiac failure | 1 (0.0) | (0.0, 0.2) |
| Myocardial infarction | 1 (0.0) | (0.0, 0.2) |
| Supraventricular tachycardia | 0 | (0.0, 0.2) |
| Congenital, familial and genetic disorders | 0 | (0.0, 0.2) |
| Thalassaemia beta | 0 | (0.0, 0.2) |
| Ear and labyrinth disorders | 1 (0.0) | (0.0, 0.2) |
| Ear pain | 1 (0.0) | (0.0, 0.2) |
| Vertigo | 0 | (0.0, 0.2) |
| Endocrine disorders | 2 (0.1) | (0.0, 0.3) |
| Hypothyroidism | 1 (0.0) | (0.0, 0.2) |
| Goitre | 0 | (0.0, 0.2) |
| Thyroid mass | 1 (0.0) | (0.0, 0.2) |
| Eye disorders | 7 (0.3) | (0.1, 0.6) |
| Photophobia | 0 | (0.0, 0.2) |
| Cataract | 1 (0.0) | (0.0, 0.2) |
| Chalazion | 1 (0.0) | (0.0, 0.2) |

**14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years**

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2230) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Diplopia | 0 | (0.0, 0.2) |
| Dry age-related macular degeneration | 1 (0.0) | (0.0, 0.2) |
| Eye pain | 0 | (0.0, 0.2) |
| Eyelid ptosis | 1 (0.0) | (0.0, 0.2) |
| Glaucoma | 1 (0.0) | (0.0, 0.2) |
| Keratitis | 1 (0.0) | (0.0, 0.2) |
| Macular degeneration | 1 (0.0) | (0.0, 0.2) |
| Ocular hyperaemia | 0 | (0.0, 0.2) |
| Vitreous detachment | 1 (0.0) | (0.0, 0.2) |
| Gastrointestinal disorders | 43 (1.9) | (1.4, 2.6) |
| Nausea | 27 (1.2) | (0.8, 1.8) |
| Diarrhoea | 8 (0.4) | (0.2, 0.7) |
| Vomiting | 5 (0.2) | (0.1, 0.5) |
| Dyspepsia | 1 (0.0) | (0.0, 0.2) |
| Gastrooesophageal reflux disease | 0 | (0.0, 0.2) |
| Abdominal pain | 0 | (0.0, 0.2) |
| Abdominal pain upper | 1 (0.0) | (0.0, 0.2) |
| Constipation | 0 | (0.0, 0.2) |
| Aphthous ulcer | 1 (0.0) | (0.0, 0.2) |
| Colitis | 1 (0.0) | (0.0, 0.2) |
| Dental caries | 0 | (0.0, 0.2) |
| Diverticulum | 1 (0.0) | (0.0, 0.2) |
| Dry mouth | 0 | (0.0, 0.2) |
| Gastric fistula | 0 | (0.0, 0.2) |
| Gastritis | 1 (0.0) | (0.0, 0.2) |
| Hiatus hernia | 1 (0.0) | (0.0, 0.2) |
| Hypoaesthesia teeth | 0 | (0.0, 0.2) |
| Inguinal hernia | 1 (0.0) | (0.0, 0.2) |
| Intestinal perforation | 0 | (0.0, 0.2) |
| Lower gastrointestinal haemorrhage | 1 (0.0) | (0.0, 0.2) |
| Oesophageal ulcer | 1 (0.0) | (0.0, 0.2) |
| Pancreatic pseudocyst | 0 | (0.0, 0.2) |
| Pancreatitis acute | 0 | (0.0, 0.2) |
| Small intestinal obstruction | 1 (0.0) | (0.0, 0.2) |
| General disorders and administration site conditions | 412 (18.5) | (16.9, 20.1) |
| Injection site pain | 240 (10.8) | (9.5, 12.1) |

**14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=2230)<br>n[b] (%) | (95% CI[c]) |
|---|---|---|
| Fatigue | 160 (7.2) | (6.1, 8.3) |
| Pyrexia | 93 (4.2) | (3.4, 5.1) |
| Chills | 85 (3.8) | (3.1, 4.7) |
| Pain | 55 (2.5) | (1.9, 3.2) |
| Malaise | 10 (0.4) | (0.2, 0.8) |
| Injection site erythema | 12 (0.5) | (0.3, 0.9) |
| Injection site swelling | 10 (0.4) | (0.2, 0.8) |
| Axillary pain | 3 (0.1) | (0.0, 0.4) |
| Asthenia | 4 (0.2) | (0.0, 0.5) |
| Injection site reaction | 1 (0.0) | (0.0, 0.2) |
| Feeling hot | 0 | (0.0, 0.2) |
| Injection site pruritus | 3 (0.1) | (0.0, 0.4) |
| Swelling | 2 (0.1) | (0.0, 0.3) |
| Injection site bruising | 1 (0.0) | (0.0, 0.2) |
| Injection site inflammation | 1 (0.0) | (0.0, 0.2) |
| Injection site oedema | 1 (0.0) | (0.0, 0.2) |
| Peripheral swelling | 2 (0.1) | (0.0, 0.3) |
| Chest discomfort | 1 (0.0) | (0.0, 0.2) |
| Chest pain | 0 | (0.0, 0.2) |
| Feeling abnormal | 0 | (0.0, 0.2) |
| Injection site induration | 0 | (0.0, 0.2) |
| Vaccination site pain | 0 | (0.0, 0.2) |
| Cyst | 1 (0.0) | (0.0, 0.2) |
| Death | 1 (0.0) | (0.0, 0.2) |
| Drug withdrawal syndrome | 0 | (0.0, 0.2) |
| Injection site discomfort | 0 | (0.0, 0.2) |
| Injection site hypoaesthesia | 1 (0.0) | (0.0, 0.2) |
| Injection site irritation | 1 (0.0) | (0.0, 0.2) |
| Injection site paraesthesia | 0 | (0.0, 0.2) |
| Injection site rash | 1 (0.0) | (0.0, 0.2) |
| Injection site vesicles | 1 (0.0) | (0.0, 0.2) |
| Injection site warmth | 1 (0.0) | (0.0, 0.2) |
| Injury associated with device | 0 | (0.0, 0.2) |
| Non-cardiac chest pain | 0 | (0.0, 0.2) |
| Sluggishness | 0 | (0.0, 0.2) |
| Vaccination site rash | 0 | (0.0, 0.2) |

**14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years**

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2230) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Hepatobiliary disorders | 0 | (0.0, 0.2) |
| Cholelithiasis | 0 | (0.0, 0.2) |
| Bile duct stone | 0 | (0.0, 0.2) |
| Immune system disorders | 1 (0.0) | (0.0, 0.2) |
| Food allergy | 1 (0.0) | (0.0, 0.2) |
| Infections and infestations | 22 (1.0) | (0.6, 1.5) |
| Cellulitis | 6 (0.3) | (0.1, 0.6) |
| Urinary tract infection | 1 (0.0) | (0.0, 0.2) |
| Acute sinusitis | 2 (0.1) | (0.0, 0.3) |
| Appendicitis | 1 (0.0) | (0.0, 0.2) |
| Herpes zoster | 0 | (0.0, 0.2) |
| Appendicitis perforated | 2 (0.1) | (0.0, 0.3) |
| Cystitis | 2 (0.1) | (0.0, 0.3) |
| Ear infection | 1 (0.0) | (0.0, 0.2) |
| Hordeolum | 0 | (0.0, 0.2) |
| Onychomycosis | 1 (0.0) | (0.0, 0.2) |
| Peritonitis | 1 (0.0) | (0.0, 0.2) |
| Tooth infection | 1 (0.0) | (0.0, 0.2) |
| Abdominal sepsis | 0 | (0.0, 0.2) |
| Abscess | 1 (0.0) | (0.0, 0.2) |
| Adenoiditis | 0 | (0.0, 0.2) |
| Anal fistula infection | 0 | (0.0, 0.2) |
| Cholangitis infective | 0 | (0.0, 0.2) |
| Conjunctivitis | 0 | (0.0, 0.2) |
| Device related infection | 1 (0.0) | (0.0, 0.2) |
| Diverticulitis | 1 (0.0) | (0.0, 0.2) |
| Gastroenteritis | 0 | (0.0, 0.2) |
| Infected dermal cyst | 1 (0.0) | (0.0, 0.2) |
| Latent tuberculosis | 0 | (0.0, 0.2) |
| Liver abscess | 1 (0.0) | (0.0, 0.2) |
| Lyme disease | 0 | (0.0, 0.2) |
| Oral herpes | 0 | (0.0, 0.2) |
| Osteomyelitis | 1 (0.0) | (0.0, 0.2) |
| Otitis externa | 0 | (0.0, 0.2) |
| Otitis media | 0 | (0.0, 0.2) |
| Otitis media acute | 1 (0.0) | (0.0, 0.2) |

## 14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=2230)<br>n[b] (%) | <br><br><br>(95% CI[c]) |
|---|---|---|
| Salmonellosis | 1 (0.0) | (0.0, 0.2) |
| Septic shock | 0 | (0.0, 0.2) |
| Sinusitis | 0 | (0.0, 0.2) |
| Varicella zoster virus infection | 1 (0.0) | (0.0, 0.2) |
| Vestibular neuronitis | 1 (0.0) | (0.0, 0.2) |
| Injury, poisoning and procedural complications | 17 (0.8) | (0.4, 1.2) |
| Fall | 3 (0.1) | (0.0, 0.4) |
| Skin laceration | 2 (0.1) | (0.0, 0.3) |
| Arthropod sting | 2 (0.1) | (0.0, 0.3) |
| Craniocerebral injury | 2 (0.1) | (0.0, 0.3) |
| Humerus fracture | 1 (0.0) | (0.0, 0.2) |
| Meniscus injury | 1 (0.0) | (0.0, 0.2) |
| Procedural pain | 0 | (0.0, 0.2) |
| Road traffic accident | 1 (0.0) | (0.0, 0.2) |
| Acetabulum fracture | 1 (0.0) | (0.0, 0.2) |
| Arthropod bite | 1 (0.0) | (0.0, 0.2) |
| Bone contusion | 0 | (0.0, 0.2) |
| Burns third degree | 1 (0.0) | (0.0, 0.2) |
| Cartilage injury | 0 | (0.0, 0.2) |
| Clavicle fracture | 1 (0.0) | (0.0, 0.2) |
| Concussion | 0 | (0.0, 0.2) |
| Exposure during pregnancy | 0 | (0.0, 0.2) |
| Joint injury | 0 | (0.0, 0.2) |
| Ligament rupture | 0 | (0.0, 0.2) |
| Ligament sprain | 0 | (0.0, 0.2) |
| Limb crushing injury | 1 (0.0) | (0.0, 0.2) |
| Limb injury | 1 (0.0) | (0.0, 0.2) |
| Muscle strain | 1 (0.0) | (0.0, 0.2) |
| Pelvic fracture | 1 (0.0) | (0.0, 0.2) |
| Periorbital haemorrhage | 1 (0.0) | (0.0, 0.2) |
| Post procedural haemorrhage | 0 | (0.0, 0.2) |
| Procedural nausea | 0 | (0.0, 0.2) |
| Rib fracture | 1 (0.0) | (0.0, 0.2) |
| Stoma complication | 0 | (0.0, 0.2) |
| Subdural haematoma | 1 (0.0) | (0.0, 0.2) |
| Wrist fracture | 1 (0.0) | (0.0, 0.2) |

## 14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2230) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Investigations | 13 (0.6) | (0.3, 1.0) |
| Body temperature increased | 11 (0.5) | (0.2, 0.9) |
| Hepatic enzyme increased | 1 (0.0) | (0.0, 0.2) |
| Blood cholesterol increased | 0 | (0.0, 0.2) |
| Blood pressure increased | 0 | (0.0, 0.2) |
| Inflammatory marker increased | 0 | (0.0, 0.2) |
| Lipase increased | 1 (0.0) | (0.0, 0.2) |
| Respiratory rate increased | 0 | (0.0, 0.2) |
| Metabolism and nutrition disorders | 15 (0.7) | (0.4, 1.1) |
| Decreased appetite | 5 (0.2) | (0.1, 0.5) |
| Hypercholesterolaemia | 4 (0.2) | (0.0, 0.5) |
| Type 2 diabetes mellitus | 1 (0.0) | (0.0, 0.2) |
| Dehydration | 1 (0.0) | (0.0, 0.2) |
| Glucose tolerance impaired | 1 (0.0) | (0.0, 0.2) |
| Hypervolaemia | 1 (0.0) | (0.0, 0.2) |
| Hypokalaemia | 1 (0.0) | (0.0, 0.2) |
| Hyponatraemia | 1 (0.0) | (0.0, 0.2) |
| Musculoskeletal and connective tissue disorders | 144 (6.5) | (5.5, 7.6) |
| Myalgia | 83 (3.7) | (3.0, 4.6) |
| Pain in extremity | 30 (1.3) | (0.9, 1.9) |
| Arthralgia | 20 (0.9) | (0.5, 1.4) |
| Neck pain | 5 (0.2) | (0.1, 0.5) |
| Back pain | 5 (0.2) | (0.1, 0.5) |
| Synovial cyst | 0 | (0.0, 0.2) |
| Joint swelling | 2 (0.1) | (0.0, 0.3) |
| Muscular weakness | 0 | (0.0, 0.2) |
| Musculoskeletal chest pain | 1 (0.0) | (0.0, 0.2) |
| Musculoskeletal stiffness | 0 | (0.0, 0.2) |
| Osteoarthritis | 1 (0.0) | (0.0, 0.2) |
| Bone cyst | 1 (0.0) | (0.0, 0.2) |
| Bone pain | 0 | (0.0, 0.2) |
| Foot deformity | 1 (0.0) | (0.0, 0.2) |
| Intervertebral disc protrusion | 1 (0.0) | (0.0, 0.2) |
| Intervertebral disc space narrowing | 1 (0.0) | (0.0, 0.2) |
| Joint effusion | 1 (0.0) | (0.0, 0.2) |
| Joint stiffness | 1 (0.0) | (0.0, 0.2) |

## 14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=2230)<br>n[b] (%) | <br><br><br>(95% CI[c]) |
|---|---|---|
| Muscle swelling | 1 (0.0) | (0.0, 0.2) |
| Musculoskeletal pain | 1 (0.0) | (0.0, 0.2) |
| Osteoporosis | 1 (0.0) | (0.0, 0.2) |
| Pain in jaw | 0 | (0.0, 0.2) |
| Rotator cuff syndrome | 1 (0.0) | (0.0, 0.2) |
| Scoliosis | 0 | (0.0, 0.2) |
| Spondylolisthesis | 1 (0.0) | (0.0, 0.2) |
| Tendonitis | 1 (0.0) | (0.0, 0.2) |
| Trigger finger | 1 (0.0) | (0.0, 0.2) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 17 (0.8) | (0.4, 1.2) |
| Basal cell carcinoma | 3 (0.1) | (0.0, 0.4) |
| Breast cancer | 2 (0.1) | (0.0, 0.3) |
| Invasive ductal breast carcinoma | 2 (0.1) | (0.0, 0.3) |
| Malignant melanoma | 2 (0.1) | (0.0, 0.3) |
| Prostate cancer | 2 (0.1) | (0.0, 0.3) |
| Acute lymphocytic leukaemia | 0 | (0.0, 0.2) |
| Brain neoplasm | 0 | (0.0, 0.2) |
| Focal nodular hyperplasia | 0 | (0.0, 0.2) |
| Follicular lymphoma | 1 (0.0) | (0.0, 0.2) |
| Granular cell tumour | 0 | (0.0, 0.2) |
| Lipoma | 0 | (0.0, 0.2) |
| Meningioma | 0 | (0.0, 0.2) |
| Nervous system neoplasm | 0 | (0.0, 0.2) |
| Ovarian cancer | 1 (0.0) | (0.0, 0.2) |
| Renal cell carcinoma | 1 (0.0) | (0.0, 0.2) |
| Skin cancer | 1 (0.0) | (0.0, 0.2) |
| Squamous cell carcinoma | 1 (0.0) | (0.0, 0.2) |
| Uterine cancer | 1 (0.0) | (0.0, 0.2) |
| Uterine leiomyoma | 0 | (0.0, 0.2) |
| Nervous system disorders | 117 (5.2) | (4.4, 6.3) |
| Headache | 99 (4.4) | (3.6, 5.4) |
| Lethargy | 8 (0.4) | (0.2, 0.7) |
| Dizziness | 2 (0.1) | (0.0, 0.3) |
| Syncope | 5 (0.2) | (0.1, 0.5) |
| Migraine | 1 (0.0) | (0.0, 0.2) |
| Hypoaesthesia | 1 (0.0) | (0.0, 0.2) |

**14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=2230)<br>n[b] (%) | (95% CI[c]) |
|---|---|---|
| Cerebrovascular accident | 2 (0.1) | (0.0, 0.3) |
| Hyperaesthesia | 1 (0.0) | (0.0, 0.2) |
| Paraesthesia | 0 | (0.0, 0.2) |
| Altered state of consciousness | 1 (0.0) | (0.0, 0.2) |
| Carpal tunnel syndrome | 0 | (0.0, 0.2) |
| Cerebral haemorrhage | 0 | (0.0, 0.2) |
| Dysgeusia | 1 (0.0) | (0.0, 0.2) |
| Intracranial aneurysm | 0 | (0.0, 0.2) |
| Migraine with aura | 1 (0.0) | (0.0, 0.2) |
| Neuralgic amyotrophy | 0 | (0.0, 0.2) |
| Parosmia | 0 | (0.0, 0.2) |
| Presyncope | 1 (0.0) | (0.0, 0.2) |
| Sciatica | 0 | (0.0, 0.2) |
| Seizure | 0 | (0.0, 0.2) |
| Somnolence | 0 | (0.0, 0.2) |
| Taste disorder | 0 | (0.0, 0.2) |
| Tension headache | 0 | (0.0, 0.2) |
| Toxic encephalopathy | 0 | (0.0, 0.2) |
| Tremor | 0 | (0.0, 0.2) |
| Pregnancy, puerperium and perinatal conditions | 0 | (0.0, 0.2) |
| Abortion spontaneous | 0 | (0.0, 0.2) |
| Pregnancy | 0 | (0.0, 0.2) |
| Psychiatric disorders | 6 (0.3) | (0.1, 0.6) |
| Depression | 2 (0.1) | (0.0, 0.3) |
| Anxiety | 2 (0.1) | (0.0, 0.3) |
| Attention deficit hyperactivity disorder | 0 | (0.0, 0.2) |
| Insomnia | 1 (0.0) | (0.0, 0.2) |
| Abnormal dreams | 0 | (0.0, 0.2) |
| Adjustment disorder with mixed anxiety and depressed mood | 0 | (0.0, 0.2) |
| Generalised anxiety disorder | 0 | (0.0, 0.2) |
| Mood altered | 0 | (0.0, 0.2) |
| Poor quality sleep | 1 (0.0) | (0.0, 0.2) |
| Stress | 0 | (0.0, 0.2) |
| Suicidal ideation | 0 | (0.0, 0.2) |
| Renal and urinary disorders | 11 (0.5) | (0.2, 0.9) |
| Nephrolithiasis | 2 (0.1) | (0.0, 0.3) |

**14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years**

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2230) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Renal cyst | 2 (0.1) | (0.0, 0.3) |
| Urinary incontinence | 2 (0.1) | (0.0, 0.3) |
| Dysuria | 1 (0.0) | (0.0, 0.2) |
| End stage renal disease | 1 (0.0) | (0.0, 0.2) |
| Haematuria | 1 (0.0) | (0.0, 0.2) |
| Renal colic | 1 (0.0) | (0.0, 0.2) |
| Stress urinary incontinence | 1 (0.0) | (0.0, 0.2) |
| Reproductive system and breast disorders | 6 (0.3) | (0.1, 0.6) |
| Atrophic vulvovaginitis | 2 (0.1) | (0.0, 0.3) |
| Menstruation irregular | 0 | (0.0, 0.2) |
| Ovarian cyst | 0 | (0.0, 0.2) |
| Breast mass | 1 (0.0) | (0.0, 0.2) |
| Breast pain | 1 (0.0) | (0.0, 0.2) |
| Heavy menstrual bleeding | 0 | (0.0, 0.2) |
| Intermenstrual bleeding | 0 | (0.0, 0.2) |
| Menopausal symptoms | 0 | (0.0, 0.2) |
| Prostatitis | 1 (0.0) | (0.0, 0.2) |
| Scrotal disorder | 1 (0.0) | (0.0, 0.2) |
| Respiratory, thoracic and mediastinal disorders | 9 (0.4) | (0.2, 0.8) |
| Asthma | 2 (0.1) | (0.0, 0.3) |
| Epistaxis | 3 (0.1) | (0.0, 0.4) |
| Nasal congestion | 2 (0.1) | (0.0, 0.3) |
| Rhinorrhoea | 1 (0.0) | (0.0, 0.2) |
| Sinus congestion | 2 (0.1) | (0.0, 0.3) |
| Acute respiratory failure | 1 (0.0) | (0.0, 0.2) |
| Dry throat | 0 | (0.0, 0.2) |
| Pharyngeal swelling | 0 | (0.0, 0.2) |
| Throat tightness | 0 | (0.0, 0.2) |
| Upper-airway cough syndrome | 0 | (0.0, 0.2) |
| Skin and subcutaneous tissue disorders | 13 (0.6) | (0.3, 1.0) |
| Hyperhidrosis | 2 (0.1) | (0.0, 0.3) |
| Night sweats | 1 (0.0) | (0.0, 0.2) |
| Rash | 3 (0.1) | (0.0, 0.4) |
| Pruritus | 1 (0.0) | (0.0, 0.2) |
| Urticaria | 1 (0.0) | (0.0, 0.2) |
| Alopecia | 0 | (0.0, 0.2) |

## 14.98. Number (%) of Participants Reporting at Least 1 Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2230) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Alopecia areata | 1 (0.0) | (0.0, 0.2) |
| Dermatitis contact | 1 (0.0) | (0.0, 0.2) |
| Dry skin | 1 (0.0) | (0.0, 0.2) |
| Erythema | 0 | (0.0, 0.2) |
| Psoriasis | 1 (0.0) | (0.0, 0.2) |
| Rash erythematous | 0 | (0.0, 0.2) |
| Rash maculo-papular | 1 (0.0) | (0.0, 0.2) |
| Xanthoma | 1 (0.0) | (0.0, 0.2) |
| Surgical and medical procedures | 2 (0.1) | (0.0, 0.3) |
| Bunion operation | 1 (0.0) | (0.0, 0.2) |
| Gastrectomy | 1 (0.0) | (0.0, 0.2) |
| Vascular disorders | 5 (0.2) | (0.1, 0.5) |
| Hypertension | 4 (0.2) | (0.0, 0.5) |
| Hot flush | 0 | (0.0, 0.2) |
| Haematoma | 1 (0.0) | (0.0, 0.2) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (09:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_all_6m_3k_age_saf

## 14.99. Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5000) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Any event | 1199 (24.0) | (22.8, 25.2) |
| Blood and lymphatic system disorders | 137 (2.7) | (2.3, 3.2) |
| Lymphadenopathy | 133 (2.7) | (2.2, 3.1) |
| Lymph node pain | 4 (0.1) | (0.0, 0.2) |
| Lymphadenitis | 2 (0.0) | (0.0, 0.1) |
| Lymphopenia | 1 (0.0) | (0.0, 0.1) |
| Neutropenia | 1 (0.0) | (0.0, 0.1) |
| Thrombocytopenia | 1 (0.0) | (0.0, 0.1) |
| Cardiac disorders | 5 (0.1) | (0.0, 0.2) |
| Palpitations | 3 (0.1) | (0.0, 0.2) |
| Tachycardia | 2 (0.0) | (0.0, 0.1) |
| Ear and labyrinth disorders | 3 (0.1) | (0.0, 0.2) |
| Vertigo | 2 (0.0) | (0.0, 0.1) |
| Ear pain | 1 (0.0) | (0.0, 0.1) |
| Eye disorders | 3 (0.1) | (0.0, 0.2) |
| Diplopia | 1 (0.0) | (0.0, 0.1) |
| Eye pain | 1 (0.0) | (0.0, 0.1) |
| Macular degeneration | 1 (0.0) | (0.0, 0.1) |
| Photophobia | 1 (0.0) | (0.0, 0.1) |
| Gastrointestinal disorders | 82 (1.6) | (1.3, 2.0) |
| Nausea | 50 (1.0) | (0.7, 1.3) |
| Diarrhoea | 26 (0.5) | (0.3, 0.8) |
| Vomiting | 12 (0.2) | (0.1, 0.4) |
| Abdominal pain | 2 (0.0) | (0.0, 0.1) |
| Abdominal pain upper | 2 (0.0) | (0.0, 0.1) |
| Dyspepsia | 2 (0.0) | (0.0, 0.1) |
| Constipation | 1 (0.0) | (0.0, 0.1) |
| Dry mouth | 1 (0.0) | (0.0, 0.1) |
| Hypoaesthesia teeth | 1 (0.0) | (0.0, 0.1) |
| General disorders and administration site conditions | 1070 (21.4) | (20.3, 22.6) |
| Injection site pain | 653 (13.1) | (12.1, 14.0) |
| Fatigue | 368 (7.4) | (6.7, 8.1) |
| Pyrexia | 250 (5.0) | (4.4, 5.6) |

## 14.99. Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5000) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Chills | 236 (4.7) | (4.1, 5.3) |
| Pain | 135 (2.7) | (2.3, 3.2) |
| Malaise | 35 (0.7) | (0.5, 1.0) |
| Injection site erythema | 21 (0.4) | (0.3, 0.6) |
| Injection site swelling | 21 (0.4) | (0.3, 0.6) |
| Axillary pain | 12 (0.2) | (0.1, 0.4) |
| Asthenia | 8 (0.2) | (0.1, 0.3) |
| Injection site reaction | 5 (0.1) | (0.0, 0.2) |
| Injection site pruritus | 4 (0.1) | (0.0, 0.2) |
| Swelling | 4 (0.1) | (0.0, 0.2) |
| Feeling hot | 3 (0.1) | (0.0, 0.2) |
| Injection site bruising | 3 (0.1) | (0.0, 0.2) |
| Injection site inflammation | 3 (0.1) | (0.0, 0.2) |
| Injection site oedema | 3 (0.1) | (0.0, 0.2) |
| Peripheral swelling | 3 (0.1) | (0.0, 0.2) |
| Chest pain | 2 (0.0) | (0.0, 0.1) |
| Feeling abnormal | 2 (0.0) | (0.0, 0.1) |
| Injection site induration | 2 (0.0) | (0.0, 0.1) |
| Vaccination site pain | 2 (0.0) | (0.0, 0.1) |
| Injection site discomfort | 1 (0.0) | (0.0, 0.1) |
| Injection site hypoaesthesia | 1 (0.0) | (0.0, 0.1) |
| Injection site irritation | 1 (0.0) | (0.0, 0.1) |
| Injection site paraesthesia | 1 (0.0) | (0.0, 0.1) |
| Injection site rash | 1 (0.0) | (0.0, 0.1) |
| Injection site vesicles | 1 (0.0) | (0.0, 0.1) |
| Injection site warmth | 1 (0.0) | (0.0, 0.1) |
| Sluggishness | 1 (0.0) | (0.0, 0.1) |
| Vaccination site rash | 1 (0.0) | (0.0, 0.1) |
| Injury, poisoning and procedural complications | 3 (0.1) | (0.0, 0.2) |
| Limb injury | 1 (0.0) | (0.0, 0.1) |
| Periorbital haemorrhage | 1 (0.0) | (0.0, 0.1) |
| Procedural pain | 1 (0.0) | (0.0, 0.1) |
| Investigations | 32 (0.6) | (0.4, 0.9) |
| Body temperature increased | 30 (0.6) | (0.4, 0.9) |
| Hepatic enzyme increased | 2 (0.0) | (0.0, 0.1) |
| Metabolism and nutrition disorders | 8 (0.2) | (0.1, 0.3) |

## 14.99. Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5000) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Decreased appetite | 7 (0.1) | (0.1, 0.3) |
| Dehydration | 1 (0.0) | (0.0, 0.1) |
| Musculoskeletal and connective tissue disorders | 321 (6.4) | (5.8, 7.1) |
| Myalgia | 239 (4.8) | (4.2, 5.4) |
| Pain in extremity | 53 (1.1) | (0.8, 1.4) |
| Arthralgia | 36 (0.7) | (0.5, 1.0) |
| Neck pain | 8 (0.2) | (0.1, 0.3) |
| Synovial cyst | 4 (0.1) | (0.0, 0.2) |
| Back pain | 2 (0.0) | (0.0, 0.1) |
| Musculoskeletal stiffness | 2 (0.0) | (0.0, 0.1) |
| Bone pain | 1 (0.0) | (0.0, 0.1) |
| Joint stiffness | 1 (0.0) | (0.0, 0.1) |
| Muscle swelling | 1 (0.0) | (0.0, 0.1) |
| Muscular weakness | 1 (0.0) | (0.0, 0.1) |
| Pain in jaw | 1 (0.0) | (0.0, 0.1) |
| Tendonitis | 1 (0.0) | (0.0, 0.1) |
| Nervous system disorders | 282 (5.6) | (5.0, 6.3) |
| Headache | 256 (5.1) | (4.5, 5.8) |
| Lethargy | 12 (0.2) | (0.1, 0.4) |
| Dizziness | 8 (0.2) | (0.1, 0.3) |
| Hyperaesthesia | 2 (0.0) | (0.0, 0.1) |
| Hypoaesthesia | 2 (0.0) | (0.0, 0.1) |
| Migraine | 2 (0.0) | (0.0, 0.1) |
| Altered state of consciousness | 1 (0.0) | (0.0, 0.1) |
| Dysgeusia | 1 (0.0) | (0.0, 0.1) |
| Neuralgic amyotrophy | 1 (0.0) | (0.0, 0.1) |
| Paraesthesia | 1 (0.0) | (0.0, 0.1) |
| Parosmia | 1 (0.0) | (0.0, 0.1) |
| Somnolence | 1 (0.0) | (0.0, 0.1) |
| Syncope | 1 (0.0) | (0.0, 0.1) |
| Taste disorder | 1 (0.0) | (0.0, 0.1) |
| Tremor | 1 (0.0) | (0.0, 0.1) |
| Psychiatric disorders | 5 (0.1) | (0.0, 0.2) |
| Insomnia | 2 (0.0) | (0.0, 0.1) |
| Abnormal dreams | 1 (0.0) | (0.0, 0.1) |
| Generalised anxiety disorder | 1 (0.0) | (0.0, 0.1) |

## 14.99. Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5000) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Poor quality sleep | 1 (0.0) | (0.0, 0.1) |
| Renal and urinary disorders | 1 (0.0) | (0.0, 0.1) |
| Dysuria | 1 (0.0) | (0.0, 0.1) |
| Reproductive system and breast disorders | 2 (0.0) | (0.0, 0.1) |
| Breast pain | 1 (0.0) | (0.0, 0.1) |
| Heavy menstrual bleeding | 1 (0.0) | (0.0, 0.1) |
| Respiratory, thoracic and mediastinal disorders | 6 (0.1) | (0.0, 0.3) |
| Rhinorrhoea | 3 (0.1) | (0.0, 0.2) |
| Dry throat | 1 (0.0) | (0.0, 0.1) |
| Nasal congestion | 1 (0.0) | (0.0, 0.1) |
| Sinus congestion | 1 (0.0) | (0.0, 0.1) |
| Throat tightness | 1 (0.0) | (0.0, 0.1) |
| Skin and subcutaneous tissue disorders | 15 (0.3) | (0.2, 0.5) |
| Hyperhidrosis | 5 (0.1) | (0.0, 0.2) |
| Night sweats | 5 (0.1) | (0.0, 0.2) |
| Pruritus | 3 (0.1) | (0.0, 0.2) |
| Rash | 1 (0.0) | (0.0, 0.1) |
| Urticaria | 1 (0.0) | (0.0, 0.1) |
| Vascular disorders | 2 (0.0) | (0.0, 0.1) |
| Hot flush | 2 (0.0) | (0.0, 0.1) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (13:12)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_6m_rel_3k_saf

## 14.100. Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=2770)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Any event | 747 (27.0) | (25.3, 28.7) |
| Blood and lymphatic system disorders | 114 (4.1) | (3.4, 4.9) |
| Lymphadenopathy | 110 (4.0) | (3.3, 4.8) |
| Lymph node pain | 4 (0.1) | (0.0, 0.4) |
| Lymphadenitis | 2 (0.1) | (0.0, 0.3) |
| Lymphopenia | 1 (0.0) | (0.0, 0.2) |
| Neutropenia | 1 (0.0) | (0.0, 0.2) |
| Thrombocytopenia | 1 (0.0) | (0.0, 0.2) |
| Cardiac disorders | 5 (0.2) | (0.1, 0.4) |
| Palpitations | 3 (0.1) | (0.0, 0.3) |
| Tachycardia | 2 (0.1) | (0.0, 0.3) |
| Ear and labyrinth disorders | 2 (0.1) | (0.0, 0.3) |
| Vertigo | 2 (0.1) | (0.0, 0.3) |
| Ear pain | 0 | (0.0, 0.1) |
| Eye disorders | 2 (0.1) | (0.0, 0.3) |
| Diplopia | 1 (0.0) | (0.0, 0.2) |
| Eye pain | 1 (0.0) | (0.0, 0.2) |
| Macular degeneration | 0 | (0.0, 0.1) |
| Photophobia | 1 (0.0) | (0.0, 0.2) |
| Gastrointestinal disorders | 47 (1.7) | (1.2, 2.2) |
| Nausea | 23 (0.8) | (0.5, 1.2) |
| Diarrhoea | 18 (0.6) | (0.4, 1.0) |
| Vomiting | 7 (0.3) | (0.1, 0.5) |
| Abdominal pain | 2 (0.1) | (0.0, 0.3) |
| Abdominal pain upper | 1 (0.0) | (0.0, 0.2) |
| Dyspepsia | 1 (0.0) | (0.0, 0.2) |
| Constipation | 1 (0.0) | (0.0, 0.2) |
| Dry mouth | 1 (0.0) | (0.0, 0.2) |
| Hypoaesthesia teeth | 1 (0.0) | (0.0, 0.2) |
| General disorders and administration site conditions | 661 (23.9) | (22.3, 25.5) |
| Injection site pain | 413 (14.9) | (13.6, 16.3) |
| Fatigue | 208 (7.5) | (6.6, 8.6) |
| Pyrexia | 157 (5.7) | (4.8, 6.6) |

## 14.100. Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2770) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Chills | 151 (5.5) | (4.6, 6.4) |
| Pain | 80 (2.9) | (2.3, 3.6) |
| Malaise | 25 (0.9) | (0.6, 1.3) |
| Injection site erythema | 9 (0.3) | (0.1, 0.6) |
| Injection site swelling | 11 (0.4) | (0.2, 0.7) |
| Axillary pain | 9 (0.3) | (0.1, 0.6) |
| Asthenia | 5 (0.2) | (0.1, 0.4) |
| Injection site reaction | 4 (0.1) | (0.0, 0.4) |
| Injection site pruritus | 1 (0.0) | (0.0, 0.2) |
| Swelling | 2 (0.1) | (0.0, 0.3) |
| Feeling hot | 3 (0.1) | (0.0, 0.3) |
| Injection site bruising | 2 (0.1) | (0.0, 0.3) |
| Injection site inflammation | 2 (0.1) | (0.0, 0.3) |
| Injection site oedema | 2 (0.1) | (0.0, 0.3) |
| Peripheral swelling | 1 (0.0) | (0.0, 0.2) |
| Chest pain | 2 (0.1) | (0.0, 0.3) |
| Feeling abnormal | 2 (0.1) | (0.0, 0.3) |
| Injection site induration | 2 (0.1) | (0.0, 0.3) |
| Vaccination site pain | 2 (0.1) | (0.0, 0.3) |
| Injection site discomfort | 1 (0.0) | (0.0, 0.2) |
| Injection site hypoaesthesia | 0 | (0.0, 0.1) |
| Injection site irritation | 0 | (0.0, 0.1) |
| Injection site paraesthesia | 1 (0.0) | (0.0, 0.2) |
| Injection site rash | 0 | (0.0, 0.1) |
| Injection site vesicles | 0 | (0.0, 0.1) |
| Injection site warmth | 0 | (0.0, 0.1) |
| Sluggishness | 1 (0.0) | (0.0, 0.2) |
| Vaccination site rash | 1 (0.0) | (0.0, 0.2) |
| Injury, poisoning and procedural complications | 1 (0.0) | (0.0, 0.2) |
| Limb injury | 0 | (0.0, 0.1) |
| Periorbital haemorrhage | 0 | (0.0, 0.1) |
| Procedural pain | 1 (0.0) | (0.0, 0.2) |
| Investigations | 20 (0.7) | (0.4, 1.1) |
| Body temperature increased | 19 (0.7) | (0.4, 1.1) |
| Hepatic enzyme increased | 1 (0.0) | (0.0, 0.2) |
| Metabolism and nutrition disorders | 3 (0.1) | (0.0, 0.3) |

**14.100. Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=2770)<br>n[b] (%) | (95% CI[c]) |
|---|---|---|
| Decreased appetite | 3 (0.1) | (0.0, 0.3) |
| Dehydration | 0 | (0.0, 0.1) |
| Musculoskeletal and connective tissue disorders | 201 (7.3) | (6.3, 8.3) |
| Myalgia | 157 (5.7) | (4.8, 6.6) |
| Pain in extremity | 25 (0.9) | (0.6, 1.3) |
| Arthralgia | 19 (0.7) | (0.4, 1.1) |
| Neck pain | 4 (0.1) | (0.0, 0.4) |
| Synovial cyst | 4 (0.1) | (0.0, 0.4) |
| Back pain | 1 (0.0) | (0.0, 0.2) |
| Musculoskeletal stiffness | 2 (0.1) | (0.0, 0.3) |
| Bone pain | 1 (0.0) | (0.0, 0.2) |
| Joint stiffness | 0 | (0.0, 0.1) |
| Muscle swelling | 0 | (0.0, 0.1) |
| Muscular weakness | 1 (0.0) | (0.0, 0.2) |
| Pain in jaw | 1 (0.0) | (0.0, 0.2) |
| Tendonitis | 0 | (0.0, 0.1) |
| Nervous system disorders | 174 (6.3) | (5.4, 7.3) |
| Headache | 158 (5.7) | (4.9, 6.6) |
| Lethargy | 4 (0.1) | (0.0, 0.4) |
| Dizziness | 7 (0.3) | (0.1, 0.5) |
| Hyperaesthesia | 1 (0.0) | (0.0, 0.2) |
| Hypoaesthesia | 1 (0.0) | (0.0, 0.2) |
| Migraine | 2 (0.1) | (0.0, 0.3) |
| Altered state of consciousness | 0 | (0.0, 0.1) |
| Dysgeusia | 0 | (0.0, 0.1) |
| Neuralgic amyotrophy | 1 (0.0) | (0.0, 0.2) |
| Paraesthesia | 1 (0.0) | (0.0, 0.2) |
| Parosmia | 1 (0.0) | (0.0, 0.2) |
| Somnolence | 1 (0.0) | (0.0, 0.2) |
| Syncope | 0 | (0.0, 0.1) |
| Taste disorder | 1 (0.0) | (0.0, 0.2) |
| Tremor | 1 (0.0) | (0.0, 0.2) |
| Psychiatric disorders | 3 (0.1) | (0.0, 0.3) |
| Insomnia | 1 (0.0) | (0.0, 0.2) |
| Abnormal dreams | 1 (0.0) | (0.0, 0.2) |
| Generalised anxiety disorder | 1 (0.0) | (0.0, 0.2) |

## 14.100. Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=2770)<br>n[b] (%) | (95% CI[c]) |
|---|---|---|
| Poor quality sleep | 0 | (0.0, 0.1) |
| Renal and urinary disorders | 0 | (0.0, 0.1) |
| Dysuria | 0 | (0.0, 0.1) |
| Reproductive system and breast disorders | 1 (0.0) | (0.0, 0.2) |
| Breast pain | 0 | (0.0, 0.1) |
| Heavy menstrual bleeding | 1 (0.0) | (0.0, 0.2) |
| Respiratory, thoracic and mediastinal disorders | 5 (0.2) | (0.1, 0.4) |
| Rhinorrhoea | 2 (0.1) | (0.0, 0.3) |
| Dry throat | 1 (0.0) | (0.0, 0.2) |
| Nasal congestion | 1 (0.0) | (0.0, 0.2) |
| Sinus congestion | 0 | (0.0, 0.1) |
| Throat tightness | 1 (0.0) | (0.0, 0.2) |
| Skin and subcutaneous tissue disorders | 9 (0.3) | (0.1, 0.6) |
| Hyperhidrosis | 3 (0.1) | (0.0, 0.3) |
| Night sweats | 4 (0.1) | (0.0, 0.4) |
| Pruritus | 2 (0.1) | (0.0, 0.3) |
| Rash | 0 | (0.0, 0.1) |
| Urticaria | 0 | (0.0, 0.1) |
| Vascular disorders | 2 (0.1) | (0.0, 0.3) |
| Hot flush | 2 (0.1) | (0.0, 0.3) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:04)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_subBIA/C4591031_A_SBLA/adae_s130_6m_rel_age_3k_saf

## 14.101. Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=2230)<br>n[b] (%) | <br><br><br>(95% CI[c]) |
|---|---|---|
| Any event | 452 (20.3) | (18.6, 22.0) |
| Blood and lymphatic system disorders | 23 (1.0) | (0.7, 1.5) |
| Lymphadenopathy | 23 (1.0) | (0.7, 1.5) |
| Lymph node pain | 0 | (0.0, 0.2) |
| Lymphadenitis | 0 | (0.0, 0.2) |
| Lymphopenia | 0 | (0.0, 0.2) |
| Neutropenia | 0 | (0.0, 0.2) |
| Thrombocytopenia | 0 | (0.0, 0.2) |
| Cardiac disorders | 0 | (0.0, 0.2) |
| Palpitations | 0 | (0.0, 0.2) |
| Tachycardia | 0 | (0.0, 0.2) |
| Ear and labyrinth disorders | 1 (0.0) | (0.0, 0.2) |
| Vertigo | 0 | (0.0, 0.2) |
| Ear pain | 1 (0.0) | (0.0, 0.2) |
| Eye disorders | 1 (0.0) | (0.0, 0.2) |
| Diplopia | 0 | (0.0, 0.2) |
| Eye pain | 0 | (0.0, 0.2) |
| Macular degeneration | 1 (0.0) | (0.0, 0.2) |
| Photophobia | 0 | (0.0, 0.2) |
| Gastrointestinal disorders | 35 (1.6) | (1.1, 2.2) |
| Nausea | 27 (1.2) | (0.8, 1.8) |
| Diarrhoea | 8 (0.4) | (0.2, 0.7) |
| Vomiting | 5 (0.2) | (0.1, 0.5) |
| Abdominal pain | 0 | (0.0, 0.2) |
| Abdominal pain upper | 1 (0.0) | (0.0, 0.2) |
| Dyspepsia | 1 (0.0) | (0.0, 0.2) |
| Constipation | 0 | (0.0, 0.2) |
| Dry mouth | 0 | (0.0, 0.2) |
| Hypoaesthesia teeth | 0 | (0.0, 0.2) |
| General disorders and administration site conditions | 409 (18.3) | (16.8, 20.0) |
| Injection site pain | 240 (10.8) | (9.5, 12.1) |
| Fatigue | 160 (7.2) | (6.1, 8.3) |
| Pyrexia | 93 (4.2) | (3.4, 5.1) |
| Chills | 85 (3.8) | (3.1, 4.7) |

## 14.101. Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=2230)<br>n[b] (%) | (95% CI[c]) |
|---|---|---|
| Pain | 55 (2.5) | (1.9, 3.2) |
| Malaise | 10 (0.4) | (0.2, 0.8) |
| Injection site erythema | 12 (0.5) | (0.3, 0.9) |
| Injection site swelling | 10 (0.4) | (0.2, 0.8) |
| Axillary pain | 3 (0.1) | (0.0, 0.4) |
| Asthenia | 3 (0.1) | (0.0, 0.4) |
| Injection site reaction | 1 (0.0) | (0.0, 0.2) |
| Injection site pruritus | 3 (0.1) | (0.0, 0.4) |
| Swelling | 2 (0.1) | (0.0, 0.3) |
| Feeling hot | 0 | (0.0, 0.2) |
| Injection site bruising | 1 (0.0) | (0.0, 0.2) |
| Injection site inflammation | 1 (0.0) | (0.0, 0.2) |
| Injection site oedema | 1 (0.0) | (0.0, 0.2) |
| Peripheral swelling | 2 (0.1) | (0.0, 0.3) |
| Chest pain | 0 | (0.0, 0.2) |
| Feeling abnormal | 0 | (0.0, 0.2) |
| Injection site induration | 0 | (0.0, 0.2) |
| Vaccination site pain | 0 | (0.0, 0.2) |
| Injection site discomfort | 0 | (0.0, 0.2) |
| Injection site hypoaesthesia | 1 (0.0) | (0.0, 0.2) |
| Injection site irritation | 1 (0.0) | (0.0, 0.2) |
| Injection site paraesthesia | 0 | (0.0, 0.2) |
| Injection site rash | 1 (0.0) | (0.0, 0.2) |
| Injection site vesicles | 1 (0.0) | (0.0, 0.2) |
| Injection site warmth | 1 (0.0) | (0.0, 0.2) |
| Sluggishness | 0 | (0.0, 0.2) |
| Vaccination site rash | 0 | (0.0, 0.2) |
| Injury, poisoning and procedural complications | 2 (0.1) | (0.0, 0.3) |
| Limb injury | 1 (0.0) | (0.0, 0.2) |
| Periorbital haemorrhage | 1 (0.0) | (0.0, 0.2) |
| Procedural pain | 0 | (0.0, 0.2) |
| Investigations | 12 (0.5) | (0.3, 0.9) |
| Body temperature increased | 11 (0.5) | (0.2, 0.9) |
| Hepatic enzyme increased | 1 (0.0) | (0.0, 0.2) |
| Metabolism and nutrition disorders | 5 (0.2) | (0.1, 0.5) |
| Decreased appetite | 4 (0.2) | (0.0, 0.5) |

**14.101. Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=2230)<br>n[b] (%) | (95% CI[c]) |
|---|---|---|
| Dehydration | 1 (0.0) | (0.0, 0.2) |
| Musculoskeletal and connective tissue disorders | 120 (5.4) | (4.5, 6.4) |
| Myalgia | 82 (3.7) | (2.9, 4.5) |
| Pain in extremity | 28 (1.3) | (0.8, 1.8) |
| Arthralgia | 17 (0.8) | (0.4, 1.2) |
| Neck pain | 4 (0.2) | (0.0, 0.5) |
| Synovial cyst | 0 | (0.0, 0.2) |
| Back pain | 1 (0.0) | (0.0, 0.2) |
| Musculoskeletal stiffness | 0 | (0.0, 0.2) |
| Bone pain | 0 | (0.0, 0.2) |
| Joint stiffness | 1 (0.0) | (0.0, 0.2) |
| Muscle swelling | 1 (0.0) | (0.0, 0.2) |
| Muscular weakness | 0 | (0.0, 0.2) |
| Pain in jaw | 0 | (0.0, 0.2) |
| Tendonitis | 1 (0.0) | (0.0, 0.2) |
| Nervous system disorders | 108 (4.8) | (4.0, 5.8) |
| Headache | 98 (4.4) | (3.6, 5.3) |
| Lethargy | 8 (0.4) | (0.2, 0.7) |
| Dizziness | 1 (0.0) | (0.0, 0.2) |
| Hyperaesthesia | 1 (0.0) | (0.0, 0.2) |
| Hypoaesthesia | 1 (0.0) | (0.0, 0.2) |
| Migraine | 0 | (0.0, 0.2) |
| Altered state of consciousness | 1 (0.0) | (0.0, 0.2) |
| Dysgeusia | 1 (0.0) | (0.0, 0.2) |
| Neuralgic amyotrophy | 0 | (0.0, 0.2) |
| Paraesthesia | 0 | (0.0, 0.2) |
| Parosmia | 0 | (0.0, 0.2) |
| Somnolence | 0 | (0.0, 0.2) |
| Syncope | 1 (0.0) | (0.0, 0.2) |
| Taste disorder | 0 | (0.0, 0.2) |
| Tremor | 0 | (0.0, 0.2) |
| Psychiatric disorders | 2 (0.1) | (0.0, 0.3) |
| Insomnia | 1 (0.0) | (0.0, 0.2) |
| Abnormal dreams | 0 | (0.0, 0.2) |
| Generalised anxiety disorder | 0 | (0.0, 0.2) |
| Poor quality sleep | 1 (0.0) | (0.0, 0.2) |

## 14.101. Number (%) of Participants Reporting at Least 1 Related Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=2230)<br>n[b] (%) | (95% CI[c]) |
|---|---|---|
| Renal and urinary disorders | 1 (0.0) | (0.0, 0.2) |
| Dysuria | 1 (0.0) | (0.0, 0.2) |
| Reproductive system and breast disorders | 1 (0.0) | (0.0, 0.2) |
| Breast pain | 1 (0.0) | (0.0, 0.2) |
| Heavy menstrual bleeding | 0 | (0.0, 0.2) |
| Respiratory, thoracic and mediastinal disorders | 1 (0.0) | (0.0, 0.2) |
| Rhinorrhoea | 1 (0.0) | (0.0, 0.2) |
| Dry throat | 0 | (0.0, 0.2) |
| Nasal congestion | 0 | (0.0, 0.2) |
| Sinus congestion | 1 (0.0) | (0.0, 0.2) |
| Throat tightness | 0 | (0.0, 0.2) |
| Skin and subcutaneous tissue disorders | 6 (0.3) | (0.1, 0.6) |
| Hyperhidrosis | 2 (0.1) | (0.0, 0.3) |
| Night sweats | 1 (0.0) | (0.0, 0.2) |
| Pruritus | 1 (0.0) | (0.0, 0.2) |
| Rash | 1 (0.0) | (0.0, 0.2) |
| Urticaria | 1 (0.0) | (0.0, 0.2) |
| Vascular disorders | 0 | (0.0, 0.2) |
| Hot flush | 0 | (0.0, 0.2) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:04)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubSIA/C4591031_A_SBLA/adae_s130_6m_rel_age_3k_saf

## 14.102. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2449, TE[b]=6.8) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 517 | 21.1 (19.5, 22.8) | 76.0 | (69.6, 82.8) |
| Related[g] | 485 | 19.8 (18.2, 21.4) | 71.3 | (65.1, 77.9) |
| Severe | 7 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.1) |
| Life-threatening | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Any serious adverse event | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 1.9) |
| Related[g] | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.5) |
| Severe | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Life-threatening | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Any nonserious adverse event | 512 | 20.9 (19.3, 22.6) | 75.3 | (68.9, 82.1) |
| Related[g] | 485 | 19.8 (18.2, 21.4) | 71.3 | (65.1, 77.9) |
| Severe | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 1.9) |
| Life-threatening | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.5) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.5) |
| Related[g] | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.5) |
| Severe | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.5) |
| Life-threatening | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.5) |
| Death | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (09:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s091_cut_age_ol_saf

## 14.103. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1947, TE[b]=5.8) | | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 330 | 16.9 (15.3, 18.7) | 56.4 | (50.5, 62.9) |
| Related[g] | 280 | 14.4 (12.9, 16.0) | 47.9 | (42.4, 53.8) |
| Severe | 10 | 0.5 (0.2, 0.9) | 1.7 | (0.8, 3.1) |
| Life-threatening | 4 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.8) |
| Any serious adverse event | 13 | 0.7 (0.4, 1.1) | 2.2 | (1.2, 3.8) |
| Related[g] | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Severe | 5 | 0.3 (0.1, 0.6) | 0.9 | (0.3, 2.0) |
| Life-threatening | 4 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.8) |
| Any nonserious adverse event | 319 | 16.4 (14.8, 18.1) | 54.6 | (48.7, 60.9) |
| Related[g] | 279 | 14.3 (12.8, 16.0) | 47.7 | (42.3, 53.7) |
| Severe | 5 | 0.3 (0.1, 0.6) | 0.9 | (0.3, 2.0) |
| Life-threatening | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Any adverse event leading to withdrawal | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Related[g] | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Severe | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) |
| Life-threatening | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Death | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |

a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (09:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_subBIA/C4591031_A_SBLA/adae_s091_cut_age_ol_saf

## 14.104. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – HIV-Positive Participants – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | | BNT162b2 (30 µg) (N[a]=23, TE[b]=0.1) | | |
| Adverse Event | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 6 | 26.1 (10.2, 48.4) | 91.6 | (33.6, 199.4) |
| Related[g] | 6 | 26.1 (10.2, 48.4) | 91.6 | (33.6, 199.4) |
| Severe | 0 | 0.0 (0.0, 14.8) | 0.0 | (0.0, 56.3) |
| Life-threatening | 0 | 0.0 (0.0, 14.8) | 0.0 | (0.0, 56.3) |
| Any serious adverse event | 0 | 0.0 (0.0, 14.8) | 0.0 | (0.0, 56.3) |
| Related[g] | 0 | 0.0 (0.0, 14.8) | 0.0 | (0.0, 56.3) |
| Severe | 0 | 0.0 (0.0, 14.8) | 0.0 | (0.0, 56.3) |
| Life-threatening | 0 | 0.0 (0.0, 14.8) | 0.0 | (0.0, 56.3) |
| Any nonserious adverse event | 6 | 26.1 (10.2, 48.4) | 91.6 | (33.6, 199.4) |
| Related[g] | 6 | 26.1 (10.2, 48.4) | 91.6 | (33.6, 199.4) |
| Severe | 0 | 0.0 (0.0, 14.8) | 0.0 | (0.0, 56.3) |
| Life-threatening | 0 | 0.0 (0.0, 14.8) | 0.0 | (0.0, 56.3) |
| Any adverse event leading to withdrawal | 0 | 0.0 (0.0, 14.8) | 0.0 | (0.0, 56.3) |
| Related[g] | 0 | 0.0 (0.0, 14.8) | 0.0 | (0.0, 56.3) |
| Severe | 0 | 0.0 (0.0, 14.8) | 0.0 | (0.0, 56.3) |
| Life-threatening | 0 | 0.0 (0.0, 14.8) | 0.0 | (0.0, 56.3) |
| Death | 0 | 0.0 (0.0, 14.8) | 0.0 | (0.0, 56.3) |

Abbreviation: HIV = human immunodeficiency virus.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event category. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
g. Assessed by the investigator as related to study intervention.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (09:05)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ~/ada2 ubBIA/C4591031 A SBLA/adae s091 cut ol hiv saf

## 14.105. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 847 | 19.3 (18.1, 20.5) | 67.0 | (62.5, 71.6) |
| Blood and lymphatic system disorders | 58 | 1.3 (1.0, 1.7) | 4.6 | (3.5, 5.9) |
| Lymph node pain | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Lymphadenopathy | 56 | 1.3 (1.0, 1.7) | 4.4 | (3.3, 5.7) |
| Cardiac disorders | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Atrial fibrillation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Palpitations | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Ear and labyrinth disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Hypoacusis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Eye disorders | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Eye irritation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Eye pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Hypermetropia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Periorbital oedema | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Gastrointestinal disorders | 50 | 1.1 (0.8, 1.5) | 4.0 | (2.9, 5.2) |
| Abdominal pain | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Abdominal pain upper | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Diarrhoea | 14 | 0.3 (0.2, 0.5) | 1.1 | (0.6, 1.9) |
| Gastrooesophageal reflux disease | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Gingival pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nausea | 28 | 0.6 (0.4, 0.9) | 2.2 | (1.5, 3.2) |
| Pancreatitis acute | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Rectal haemorrhage | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Small intestinal obstruction | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Toothache | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Vomiting | 10 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.5) |
| General disorders and administration site conditions | 690 | 15.7 (14.6, 16.8) | 54.6 | (50.6, 58.8) |
| Asthenia | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.9) |
| Axillary pain | 11 | 0.3 (0.1, 0.4) | 0.9 | (0.4, 1.6) |
| Capsular contracture associated with breast implant | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Chills | 103 | 2.3 (1.9, 2.8) | 8.1 | (6.6, 9.9) |
| Death | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Fatigue | 216 | 4.9 (4.3, 5.6) | 17.1 | (14.9, 19.5) |
| Feeling abnormal | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Feeling hot | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

## 14.105. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Injection site bruising | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Injection site discomfort | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injection site erythema | 10 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.5) |
| Injection site nodule | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injection site pain | 394 | 9.0 (8.1, 9.8) | 31.2 | (28.1, 34.4) |
| Injection site pruritus | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Injection site rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injection site swelling | 6 | 0.1 (0.1, 0.3) | 0.5 | (0.2, 1.0) |
| Injection site warmth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Malaise | 12 | 0.3 (0.1, 0.5) | 0.9 | (0.5, 1.7) |
| Pain | 124 | 2.8 (2.3, 3.3) | 9.6 | (7.9, 11.4) |
| Peripheral swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pyrexia | 133 | 3.0 (2.5, 3.6) | 10.5 | (8.8, 12.5) |
| Sudden cardiac death | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Swelling | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Swelling face | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Vessel puncture site bruise | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Infections and infestations | 22 | 0.5 (0.3, 0.8) | 1.7 | (1.1, 2.6) |
| COVID-19 pneumonia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Cellulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Diverticulitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Ear infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Eye infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Herpes zoster | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Kidney infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Localised infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Lyme disease | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Ophthalmic herpes zoster | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Otitis externa | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Otitis media | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Paronychia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pneumonia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Sinusitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Skin infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Urinary tract infection | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.9) |
| Injury, poisoning and procedural complications | 22 | 0.5 (0.3, 0.8) | 1.7 | (1.1, 2.6) |
| Clavicle fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

## 14.105. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Corneal abrasion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Exposure during pregnancy | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Fall | 6 | 0.1 (0.1, 0.3) | 0.5 | (0.2, 1.0) |
| Femur fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Hand fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Ligament sprain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Meniscus injury | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Multiple injuries | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Muscle rupture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Muscle strain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Road traffic accident | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Skin abrasion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Skin laceration | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Sternal fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Tooth fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Venom poisoning | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Investigations | 20 | 0.5 (0.3, 0.7) | 1.6 | (1.0, 2.4) |
| Blood cholesterol increased | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Body temperature increased | 16 | 0.4 (0.2, 0.6) | 1.3 | (0.7, 2.1) |
| Heart rate increased | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Metabolism and nutrition disorders | 7 | 0.2 (0.1, 0.3) | 0.6 | (0.2, 1.1) |
| Decreased appetite | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Dehydration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Diabetes mellitus | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Dyslipidaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Musculoskeletal and connective tissue disorders | 158 | 3.6 (3.1, 4.2) | 12.5 | (10.6, 14.6) |
| Arthralgia | 14 | 0.3 (0.2, 0.5) | 1.1 | (0.6, 1.9) |
| Back pain | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Bursitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Costochondritis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Muscle fatigue | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Muscle spasms | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Myalgia | 106 | 2.4 (2.0, 2.9) | 8.4 | (6.9, 10.1) |
| Neck pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Osteoarthritis | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.9) |
| Pain in extremity | 23 | 0.5 (0.3, 0.8) | 1.8 | (1.2, 2.7) |
| Synovial cyst | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |

## 14.105. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Trigger finger | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Adrenocortical carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Basal cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Biliary neoplasm | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Endometrial cancer stage III | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Metastases to vagina | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Papillary serous endometrial carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nervous system disorders | 154 | 3.5 (3.0, 4.1) | 12.2 | (10.3, 14.3) |
| Balance disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Carpal tunnel syndrome | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Disturbance in attention | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Dizziness | 9 | 0.2 (0.1, 0.4) | 0.7 | (0.3, 1.4) |
| Headache | 137 | 3.1 (2.6, 3.7) | 10.8 | (9.1, 12.8) |
| Hyperaesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Lethargy | 6 | 0.1 (0.1, 0.3) | 0.5 | (0.2, 1.0) |
| Paraesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Sinus headache | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Somnolence | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Syncope | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Tremor | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Psychiatric disorders | 6 | 0.1 (0.1, 0.3) | 0.5 | (0.2, 1.0) |
| Anxiety | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Depression | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Disorientation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Major depression | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Poor quality sleep | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Restlessness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Renal and urinary disorders | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Chronic kidney disease | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Haematuria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Urinary incontinence | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Reproductive system and breast disorders | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Benign prostatic hyperplasia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nipple pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

## 14.105. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Respiratory, thoracic and mediastinal disorders | 8 | 0.2 (0.1, 0.4) | 0.6 | (0.3, 1.2) |
| Chronic obstructive pulmonary disease | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Cough | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nasal congestion | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Oropharyngeal pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Rhinorrhoea | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Skin and subcutaneous tissue disorders | 11 | 0.3 (0.1, 0.4) | 0.9 | (0.4, 1.6) |
| Alopecia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Dermatitis atopic | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Erythema | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Hyperhidrosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Night sweats | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Pruritus | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Urticaria | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Vascular disorders | 9 | 0.2 (0.1, 0.4) | 0.7 | (0.3, 1.4) |
| Deep vein thrombosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Haematoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Hot flush | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Hypertension | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Lymphoedema | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Superficial vein thrombosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (07:56)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_cut_ol_saf

## 14.106. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2449, TE[b]=6.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 517 | 21.1 (19.5, 22.8) | 76.0 | (69.6, 82.8) |
| Blood and lymphatic system disorders | 45 | 1.8 (1.3, 2.5) | 6.6 | (4.8, 8.9) |
| Lymph node pain | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.3) |
| Lymphadenopathy | 43 | 1.8 (1.3, 2.4) | 6.3 | (4.6, 8.5) |
| Cardiac disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Palpitations | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Ear and labyrinth disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Hypoacusis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Eye disorders | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.3) |
| Eye irritation | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Eye pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Periorbital oedema | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Gastrointestinal disorders | 28 | 1.1 (0.8, 1.6) | 4.1 | (2.7, 5.9) |
| Abdominal pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Diarrhoea | 8 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.3) |
| Nausea | 16 | 0.7 (0.4, 1.1) | 2.4 | (1.3, 3.8) |
| Pancreatitis acute | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Vomiting | 7 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.1) |
| General disorders and administration site conditions | 433 | 17.7 (16.2, 19.3) | 63.7 | (57.8, 69.9) |
| Asthenia | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.3) |
| Axillary pain | 7 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.1) |
| Capsular contracture associated with breast implant | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Chills | 63 | 2.6 (2.0, 3.3) | 9.3 | (7.1, 11.8) |
| Fatigue | 141 | 5.8 (4.9, 6.8) | 20.7 | (17.4, 24.4) |
| Feeling abnormal | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Feeling hot | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Injection site bruising | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Injection site erythema | 7 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.1) |
| Injection site nodule | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Injection site pain | 244 | 10.0 (8.8, 11.2) | 35.9 | (31.5, 40.7) |
| Injection site swelling | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) |
| Injection site warmth | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Malaise | 8 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.3) |

## 14.106. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2449, TE[b]=6.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Pain | 82 | 3.3 (2.7, 4.1) | 12.1 | (9.6, 15.0) |
| Peripheral swelling | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Pyrexia | 85 | 3.5 (2.8, 4.3) | 12.5 | (10.0, 15.5) |
| Swelling | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) |
| Swelling face | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Vessel puncture site bruise | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Infections and infestations | 8 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.3) |
| Diverticulitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Kidney infection | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Lyme disease | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Otitis externa | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Otitis media | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Paronychia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Pneumonia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Skin infection | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Injury, poisoning and procedural complications | 10 | 0.4 (0.2, 0.7) | 1.5 | (0.7, 2.7) |
| Clavicle fracture | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Exposure during pregnancy | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Fall | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Ligament sprain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Meniscus injury | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Multiple injuries | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Muscle rupture | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Road traffic accident | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Skin abrasion | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Venom poisoning | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Investigations | 16 | 0.7 (0.4, 1.1) | 2.4 | (1.3, 3.8) |
| Blood cholesterol increased | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Body temperature increased | 13 | 0.5 (0.3, 0.9) | 1.9 | (1.0, 3.3) |
| Heart rate increased | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Metabolism and nutrition disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Decreased appetite | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Dehydration | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Musculoskeletal and connective tissue disorders | 100 | 4.1 (3.3, 4.9) | 14.7 | (12.0, 17.9) |
| Arthralgia | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 1.9) |
| Back pain | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.3) |

## 14.106. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2449, TE[b]=6.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Costochondritis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Muscle fatigue | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Muscle spasms | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Myalgia | 75 | 3.1 (2.4, 3.8) | 11.0 | (8.7, 13.8) |
| Neck pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Pain in extremity | 10 | 0.4 (0.2, 0.7) | 1.5 | (0.7, 2.7) |
| Synovial cyst | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) |
| Trigger finger | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Nervous system disorders | 100 | 4.1 (3.3, 4.9) | 14.7 | (12.0, 17.9) |
| Dizziness | 5 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.7) |
| Headache | 87 | 3.6 (2.9, 4.4) | 12.8 | (10.2, 15.8) |
| Lethargy | 5 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.7) |
| Paraesthesia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Somnolence | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.3) |
| Syncope | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Psychiatric disorders | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) |
| Anxiety | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Depression | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Major depression | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Poor quality sleep | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Restlessness | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Renal and urinary disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Respiratory, thoracic and mediastinal disorders | 5 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.7) |
| Cough | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Nasal congestion | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Oropharyngeal pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Rhinorrhoea | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Skin and subcutaneous tissue disorders | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 1.9) |
| Dermatitis atopic | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Erythema | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Night sweats | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Pruritus | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Vascular disorders | 7 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.1) |
| Deep vein thrombosis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |

## 14.106. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2449, TE[b]=6.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Haematoma | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Hot flush | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Hypertension | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Lymphoedema | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.3) |
| Superficial vein thrombosis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:09)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_age_ol_saf

## 14.107. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1947, TE[b]=5.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 330 | 16.9 (15.3, 18.7) | 56.4 | (50.5, 62.9) |
| Blood and lymphatic system disorders | 13 | 0.7 (0.4, 1.1) | 2.2 | (1.2, 3.8) |
| Lymphadenopathy | 13 | 0.7 (0.4, 1.1) | 2.2 | (1.2, 3.8) |
| Cardiac disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Atrial fibrillation | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Eye disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Hypermetropia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Gastrointestinal disorders | 22 | 1.1 (0.7, 1.7) | 3.8 | (2.4, 5.7) |
| Abdominal pain | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Abdominal pain upper | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Diarrhoea | 6 | 0.3 (0.1, 0.7) | 1.0 | (0.4, 2.2) |
| Gastrooesophageal reflux disease | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Gingival pain | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Nausea | 12 | 0.6 (0.3, 1.1) | 2.1 | (1.1, 3.6) |
| Rectal haemorrhage | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Small intestinal obstruction | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Toothache | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Vomiting | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| General disorders and administration site conditions | 257 | 13.2 (11.7, 14.8) | 44.0 | (38.8, 49.7) |
| Asthenia | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Axillary pain | 4 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.8) |
| Chills | 40 | 2.1 (1.5, 2.8) | 6.8 | (4.9, 9.3) |
| Death | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Fatigue | 75 | 3.9 (3.0, 4.8) | 12.8 | (10.1, 16.1) |
| Injection site bruising | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Injection site discomfort | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Injection site erythema | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Injection site pain | 150 | 7.7 (6.6, 9.0) | 25.7 | (21.7, 30.1) |
| Injection site pruritus | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Injection site rash | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Injection site swelling | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Malaise | 4 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.8) |
| Pain | 39 | 2.0 (1.4, 2.7) | 6.7 | (4.7, 9.1) |
| Pyrexia | 48 | 2.5 (1.8, 3.3) | 8.2 | (6.1, 10.9) |
| Sudden cardiac death | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |

## 14.107. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1947, TE[b]=5.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Infections and infestations | 14 | 0.7 (0.4, 1.2) | 2.4 | (1.3, 4.0) |
| COVID-19 pneumonia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Cellulitis | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Diverticulitis | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Ear infection | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Eye infection | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Herpes zoster | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Localised infection | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Ophthalmic herpes zoster | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Sinusitis | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Urinary tract infection | 5 | 0.3 (0.1, 0.6) | 0.9 | (0.3, 2.0) |
| Injury, poisoning and procedural complications | 12 | 0.6 (0.3, 1.1) | 2.1 | (1.1, 3.6) |
| Corneal abrasion | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Fall | 5 | 0.3 (0.1, 0.6) | 0.9 | (0.3, 2.0) |
| Femur fracture | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Hand fracture | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Ligament sprain | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Muscle strain | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Road traffic accident | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Skin laceration | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Sternal fracture | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Tooth fracture | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Investigations | 4 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.8) |
| Body temperature increased | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Heart rate increased | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Metabolism and nutrition disorders | 5 | 0.3 (0.1, 0.6) | 0.9 | (0.3, 2.0) |
| Decreased appetite | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Diabetes mellitus | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Dyslipidaemia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Musculoskeletal and connective tissue disorders | 58 | 3.0 (2.3, 3.8) | 9.9 | (7.5, 12.8) |
| Arthralgia | 8 | 0.4 (0.2, 0.8) | 1.4 | (0.6, 2.7) |
| Back pain | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Bursitis | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Muscle fatigue | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Muscle spasms | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Myalgia | 31 | 1.6 (1.1, 2.3) | 5.3 | (3.6, 7.5) |

## 14.107. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1947, TE[b]=5.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Osteoarthritis | 5 | 0.3 (0.1, 0.6) | 0.9 | (0.3, 2.0) |
| Pain in extremity | 13 | 0.7 (0.4, 1.1) | 2.2 | (1.2, 3.8) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 4 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.8) |
| Adrenocortical carcinoma | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Basal cell carcinoma | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Biliary neoplasm | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Endometrial cancer stage III | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Metastases to vagina | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Papillary serous endometrial carcinoma | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Nervous system disorders | 54 | 2.8 (2.1, 3.6) | 9.2 | (6.9, 12.1) |
| Balance disorder | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Carpal tunnel syndrome | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Disturbance in attention | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Dizziness | 4 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.8) |
| Headache | 50 | 2.6 (1.9, 3.4) | 8.6 | (6.3, 11.3) |
| Hyperaesthesia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Lethargy | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Sinus headache | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Tremor | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Psychiatric disorders | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Disorientation | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Poor quality sleep | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Renal and urinary disorders | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Chronic kidney disease | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Haematuria | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Urinary incontinence | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Reproductive system and breast disorders | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Benign prostatic hyperplasia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Nipple pain | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Respiratory, thoracic and mediastinal disorders | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Chronic obstructive pulmonary disease | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Nasal congestion | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Rhinorrhoea | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Skin and subcutaneous tissue disorders | 5 | 0.3 (0.1, 0.6) | 0.9 | (0.3, 2.0) |

## 14.107. Incidence Rates of at Least 1 Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1947, TE[b]=5.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Alopecia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Hyperhidrosis | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Night sweats | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Rash | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Urticaria | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Vascular disorders | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Hypertension | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:09)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_age_ol_saf

## 14.108. Incidence Rates of at Least 1 Related Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 765 | 17.4 (16.3, 18.6) | 60.5 | (56.3, 64.9) |
| Blood and lymphatic system disorders | 58 | 1.3 (1.0, 1.7) | 4.6 | (3.5, 5.9) |
| Lymph node pain | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Lymphadenopathy | 56 | 1.3 (1.0, 1.7) | 4.4 | (3.3, 5.7) |
| Eye disorders | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Eye pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Periorbital oedema | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Gastrointestinal disorders | 42 | 1.0 (0.7, 1.3) | 3.3 | (2.4, 4.5) |
| Abdominal pain | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Abdominal pain upper | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Diarrhoea | 13 | 0.3 (0.2, 0.5) | 1.0 | (0.5, 1.8) |
| Gingival pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nausea | 26 | 0.6 (0.4, 0.9) | 2.1 | (1.3, 3.0) |
| Toothache | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Vomiting | 10 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.5) |
| General disorders and administration site conditions | 683 | 15.5 (14.5, 16.6) | 54.0 | (50.0, 58.2) |
| Asthenia | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Axillary pain | 11 | 0.3 (0.1, 0.4) | 0.9 | (0.4, 1.6) |
| Chills | 102 | 2.3 (1.9, 2.8) | 8.1 | (6.6, 9.8) |
| Fatigue | 214 | 4.9 (4.3, 5.5) | 16.9 | (14.7, 19.3) |
| Feeling abnormal | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Feeling hot | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injection site bruising | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Injection site discomfort | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injection site erythema | 10 | 0.2 (0.1, 0.4) | 0.8 | (0.4, 1.5) |
| Injection site nodule | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injection site pain | 394 | 9.0 (8.1, 9.8) | 31.2 | (28.1, 34.4) |
| Injection site pruritus | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Injection site rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injection site swelling | 6 | 0.1 (0.1, 0.3) | 0.5 | (0.2, 1.0) |
| Injection site warmth | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Malaise | 12 | 0.3 (0.1, 0.5) | 0.9 | (0.5, 1.7) |
| Pain | 120 | 2.7 (2.3, 3.3) | 9.5 | (7.9, 11.3) |
| Peripheral swelling | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pyrexia | 133 | 3.0 (2.5, 3.6) | 10.5 | (8.8, 12.5) |

## 14.108. Incidence Rates of at Least 1 Related Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Swelling | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Vessel puncture site bruise | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Infections and infestations | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Cellulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injury, poisoning and procedural complications | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Fall | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Investigations | 19 | 0.4 (0.3, 0.7) | 1.5 | (0.9, 2.3) |
| Body temperature increased | 16 | 0.4 (0.2, 0.6) | 1.3 | (0.7, 2.1) |
| Heart rate increased | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Metabolism and nutrition disorders | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.9) |
| Decreased appetite | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Dehydration | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Musculoskeletal and connective tissue disorders | 145 | 3.3 (2.8, 3.9) | 11.5 | (9.7, 13.5) |
| Arthralgia | 13 | 0.3 (0.2, 0.5) | 1.0 | (0.5, 1.8) |
| Back pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Muscle fatigue | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Muscle spasms | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Myalgia | 105 | 2.4 (2.0, 2.9) | 8.3 | (6.8, 10.0) |
| Neck pain | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Pain in extremity | 22 | 0.5 (0.3, 0.8) | 1.7 | (1.1, 2.6) |
| Synovial cyst | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Nervous system disorders | 148 | 3.4 (2.9, 3.9) | 11.7 | (9.9, 13.7) |
| Balance disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Disturbance in attention | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Dizziness | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.9) |
| Headache | 134 | 3.0 (2.6, 3.6) | 10.6 | (8.9, 12.5) |
| Hyperaesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Lethargy | 6 | 0.1 (0.1, 0.3) | 0.5 | (0.2, 1.0) |
| Paraesthesia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Sinus headache | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Somnolence | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Syncope | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Tremor | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Psychiatric disorders | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Disorientation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Poor quality sleep | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |

## 14.108. Incidence Rates of at Least 1 Related Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Restlessness | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Respiratory, thoracic and mediastinal disorders | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.9) |
| Chronic obstructive pulmonary disease | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nasal congestion | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Rhinorrhoea | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Skin and subcutaneous tissue disorders | 9 | 0.2 (0.1, 0.4) | 0.7 | (0.3, 1.4) |
| Dermatitis atopic | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Erythema | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Hyperhidrosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Night sweats | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Pruritus | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Rash | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Vascular disorders | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Haematoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Lymphoedema | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (07:56)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBLA/C4591031_A_SBLA/adae_s131_cut_rel_ol_saf

## 14.109. Incidence Rates of at Least 1 Related Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2449, TE[b]=6.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 485 | 19.8 (18.2, 21.4) | 71.3 | (65.1, 77.9) |
| Blood and lymphatic system disorders | 45 | 1.8 (1.3, 2.5) | 6.6 | (4.8, 8.9) |
| Lymph node pain | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.3) |
| Lymphadenopathy | 43 | 1.8 (1.3, 2.4) | 6.3 | (4.6, 8.5) |
| Eye disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Eye pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Periorbital oedema | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Gastrointestinal disorders | 23 | 0.9 (0.6, 1.4) | 3.4 | (2.1, 5.1) |
| Abdominal pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Diarrhoea | 7 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.1) |
| Nausea | 14 | 0.6 (0.3, 1.0) | 2.1 | (1.1, 3.5) |
| Vomiting | 7 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.1) |
| General disorders and administration site conditions | 429 | 17.5 (16.0, 19.1) | 63.1 | (57.2, 69.3) |
| Asthenia | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.3) |
| Axillary pain | 7 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.1) |
| Chills | 62 | 2.5 (1.9, 3.2) | 9.1 | (7.0, 11.7) |
| Fatigue | 139 | 5.7 (4.8, 6.7) | 20.4 | (17.2, 24.1) |
| Feeling abnormal | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Feeling hot | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Injection site bruising | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Injection site erythema | 7 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.1) |
| Injection site nodule | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Injection site pain | 244 | 10.0 (8.8, 11.2) | 35.9 | (31.5, 40.7) |
| Injection site swelling | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) |
| Injection site warmth | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Malaise | 8 | 0.3 (0.1, 0.6) | 1.2 | (0.5, 2.3) |
| Pain | 81 | 3.3 (2.6, 4.1) | 11.9 | (9.5, 14.8) |
| Peripheral swelling | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Pyrexia | 85 | 3.5 (2.8, 4.3) | 12.5 | (10.0, 15.5) |
| Swelling | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) |
| Vessel puncture site bruise | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Injury, poisoning and procedural complications | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Fall | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Investigations | 15 | 0.6 (0.3, 1.0) | 2.2 | (1.2, 3.6) |

## 14.109. Incidence Rates of at Least 1 Related Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2449, TE[b]=6.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Body temperature increased | 13 | 0.5 (0.3, 0.9) | 1.9 | (1.0, 3.3) |
| Heart rate increased | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Metabolism and nutrition disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Decreased appetite | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Dehydration | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Musculoskeletal and connective tissue disorders | 96 | 3.9 (3.2, 4.8) | 14.1 | (11.4, 17.2) |
| Arthralgia | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 1.9) |
| Back pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Muscle fatigue | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Muscle spasms | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Myalgia | 75 | 3.1 (2.4, 3.8) | 11.0 | (8.7, 13.8) |
| Neck pain | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Pain in extremity | 10 | 0.4 (0.2, 0.7) | 1.5 | (0.7, 2.7) |
| Synovial cyst | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) |
| Nervous system disorders | 97 | 4.0 (3.2, 4.8) | 14.3 | (11.6, 17.4) |
| Dizziness | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) |
| Headache | 85 | 3.5 (2.8, 4.3) | 12.5 | (10.0, 15.5) |
| Lethargy | 5 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.7) |
| Paraesthesia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Somnolence | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.3) |
| Syncope | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Psychiatric disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Poor quality sleep | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Restlessness | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Respiratory, thoracic and mediastinal disorders | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.3) |
| Nasal congestion | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Rhinorrhoea | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Skin and subcutaneous tissue disorders | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 1.9) |
| Dermatitis atopic | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Erythema | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Night sweats | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Pruritus | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Vascular disorders | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) |
| Haematoma | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Lymphoedema | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.3) |

## 14.109. Incidence Rates of at Least 1 Related Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2449, TE[b]=6.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:11)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_rel_age_ol_saf

## 14.110. Incidence Rates of at Least 1 Related Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1947, TE[b]=5.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 280 | 14.4 (12.9, 16.0) | 47.9 | (42.4, 53.8) |
| Blood and lymphatic system disorders | 13 | 0.7 (0.4, 1.1) | 2.2 | (1.2, 3.8) |
| Lymphadenopathy | 13 | 0.7 (0.4, 1.1) | 2.2 | (1.2, 3.8) |
| Gastrointestinal disorders | 19 | 1.0 (0.6, 1.5) | 3.3 | (2.0, 5.1) |
| Abdominal pain | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Abdominal pain upper | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Diarrhoea | 6 | 0.3 (0.1, 0.7) | 1.0 | (0.4, 2.2) |
| Gingival pain | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Nausea | 12 | 0.6 (0.3, 1.1) | 2.1 | (1.1, 3.6) |
| Toothache | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Vomiting | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| General disorders and administration site conditions | 254 | 13.0 (11.6, 14.6) | 43.4 | (38.3, 49.1) |
| Asthenia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Axillary pain | 4 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.8) |
| Chills | 40 | 2.1 (1.5, 2.8) | 6.8 | (4.9, 9.3) |
| Fatigue | 75 | 3.9 (3.0, 4.8) | 12.8 | (10.1, 16.1) |
| Injection site bruising | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Injection site discomfort | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Injection site erythema | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Injection site pain | 150 | 7.7 (6.6, 9.0) | 25.7 | (21.7, 30.1) |
| Injection site pruritus | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Injection site rash | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Injection site swelling | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Malaise | 4 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.8) |
| Pain | 39 | 2.0 (1.4, 2.7) | 6.7 | (4.7, 9.1) |
| Pyrexia | 48 | 2.5 (1.8, 3.3) | 8.2 | (6.1, 10.9) |
| Infections and infestations | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Cellulitis | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Investigations | 4 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.8) |
| Body temperature increased | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Heart rate increased | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Metabolism and nutrition disorders | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Decreased appetite | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Musculoskeletal and connective tissue disorders | 49 | 2.5 (1.9, 3.3) | 8.4 | (6.2, 11.1) |

## 14.110. Incidence Rates of at Least 1 Related Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1947, TE[b]=5.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Arthralgia | 7 | 0.4 (0.1, 0.7) | 1.2 | (0.5, 2.5) |
| Back pain | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Muscle fatigue | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Muscle spasms | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Myalgia | 30 | 1.5 (1.0, 2.2) | 5.1 | (3.5, 7.3) |
| Pain in extremity | 12 | 0.6 (0.3, 1.1) | 2.1 | (1.1, 3.6) |
| Nervous system disorders | 51 | 2.6 (2.0, 3.4) | 8.7 | (6.5, 11.5) |
| Balance disorder | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Disturbance in attention | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Dizziness | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Headache | 49 | 2.5 (1.9, 3.3) | 8.4 | (6.2, 11.1) |
| Hyperaesthesia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Lethargy | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Sinus headache | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Tremor | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Psychiatric disorders | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Disorientation | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Poor quality sleep | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Respiratory, thoracic and mediastinal disorders | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Chronic obstructive pulmonary disease | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Nasal congestion | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Skin and subcutaneous tissue disorders | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Hyperhidrosis | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Night sweats | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Rash | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |

## 14.110. Incidence Rates of at Least 1 Related Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1947, TE[b]=5.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:11)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_rel_age_ol_saf

## 14.111. Number (%) of Participants Reporting at Least 1 Immediate Adverse Event After BNT162b2 Booster Vaccination, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Any event | 8 (0.2) | (0.1, 0.4) |
| General disorders and administration site conditions | 6 (0.1) | (0.1, 0.3) |
| Injection site pain | 5 (0.1) | (0.0, 0.3) |
| Fatigue | 1 (0.0) | (0.0, 0.1) |
| Musculoskeletal and connective tissue disorders | 2 (0.0) | (0.0, 0.2) |
| Back pain | 1 (0.0) | (0.0, 0.1) |
| Pain in extremity | 1 (0.0) | (0.0, 0.1) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (13:12)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_imm_ol_saf

## 14.112. Number (%) of Participants Reporting at Least 1 Immediate Adverse Event After BNT162b2 Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period –Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | |
|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2449) | |
| System Organ Class<br>Preferred Term | n[b] (%) | (95% CI[c]) |
| Any event | 4 (0.2) | (0.0, 0.4) |
| General disorders and administration site conditions | 4 (0.2) | (0.0, 0.4) |
| Injection site pain | 3 (0.1) | (0.0, 0.4) |
| Fatigue | 1 (0.0) | (0.0, 0.2) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:25)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_imm_age_ol_saf

## 14.113. Number (%) of Participants Reporting at Least 1 Immediate Adverse Event After BNT162b2 Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period –Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: >55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=1947)<br>n[b] (%) | <br><br><br>(95% CI[c]) |
|---|---|---|
| Any event | 4 (0.2) | (0.1, 0.5) |
| General disorders and administration site conditions | 2 (0.1) | (0.0, 0.4) |
| Injection site pain | 2 (0.1) | (0.0, 0.4) |
| Musculoskeletal and connective tissue disorders | 2 (0.1) | (0.0, 0.4) |
| Back pain | 1 (0.1) | (0.0, 0.3) |
| Pain in extremity | 1 (0.1) | (0.0, 0.3) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:25)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_sl30_cut_imm_age_ol_saf

## 14.114. Incidence Rates of at Least 1 Severe Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 17 | 0.4 (0.2, 0.6) | 1.3 | (0.8, 2.2) |
| Cardiac disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Atrial fibrillation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Gastrointestinal disorders | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Pancreatitis acute | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| General disorders and administration site conditions | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.9) |
| Chills | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Fatigue | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Pyrexia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Infections and infestations | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| COVID-19 pneumonia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Cellulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Musculoskeletal and connective tissue disorders | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.9) |
| Arthralgia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Costochondritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Myalgia | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Neck pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Biliary neoplasm | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Nervous system disorders | 6 | 0.1 (0.1, 0.3) | 0.5 | (0.2, 1.0) |
| Balance disorder | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Headache | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.9) |

## 14.114. Incidence Rates of at Least 1 Severe Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:14) Source Data: adae Table Generation: 14MAR2022 (07:56)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_cut_sev_or_saf

## 14.115. Incidence Rates of at Least 1 Severe Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2449, TE[b]=6.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 7 | 0.3 (0.1, 0.6) | 1.0 | (0.4, 2.1) |
| Gastrointestinal disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Pancreatitis acute | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| General disorders and administration site conditions | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Fatigue | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Musculoskeletal and connective tissue disorders | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.5) |
| Costochondritis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Myalgia | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Neck pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Nervous system disorders | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.3) |
| Headache | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.3) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:17)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBJA/C4591031_A_SBLA/adae_s130_cut_sev_age_ol_saf

## 14.116. Incidence Rates of at Least 1 Severe Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1947, TE[b]=5.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 10 | 0.5 (0.2, 0.9) | 1.7 | (0.8, 3.1) |
| Cardiac disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Atrial fibrillation | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Gastrointestinal disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Small intestinal obstruction | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| General disorders and administration site conditions | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Chills | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Pyrexia | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Infections and infestations | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| COVID-19 pneumonia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Cellulitis | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Musculoskeletal and connective tissue disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Arthralgia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Biliary neoplasm | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Nervous system disorders | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Balance disorder | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Headache | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:17)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_sev_age_ol_saf

## 14.117. Incidence Rates of at Least 1 Life-Threatening Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 5 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 0.9) |
| General disorders and administration site conditions | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Death | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Sudden cardiac death | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Injury, poisoning and procedural complications | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Fall | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Femur fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Multiple injuries | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Road traffic accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Adrenocortical carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (13:12)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_life_ol_saf

## 14.118. Incidence Rates of at Least 1 Life-Threatening Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2449, TE[b]=6.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Injury, poisoning and procedural complications | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Multiple injuries | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Road traffic accident | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:29)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_life_age_ol_saf

## 14.119. Incidence Rates of at Least 1 Life-Threatening Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1947, TE[b]=5.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 4 | 0.2 (0.1, 0.5) | 0.7 | (0.2, 1.8) |
| General disorders and administration site conditions | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Death | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Sudden cardiac death | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Injury, poisoning and procedural complications | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Fall | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Femur fracture | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Adrenocortical carcinoma | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:29)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_life_age_ol_saf

## 14.120. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 15 | 0.5 (0.3, 0.9) | 2.1 | (1.2, 3.4) | 14 | 0.5 (0.3, 0.8) | 2.2 | (1.2, 3.7) |
| Cardiac disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Tachycardia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Endocrine disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Goitre | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Gastrointestinal disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Gastric fistula | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Small intestinal obstruction | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| General disorders and administration site conditions | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Hepatobiliary disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Bile duct stone | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Infections and infestations | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Appendicitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Septic shock | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Injury, poisoning and procedural complications | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Humerus fracture | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Ligament rupture | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Stoma complication | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Investigations | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Hepatic enzyme increased | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Musculoskeletal and connective tissue disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Back pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |

## 14.120. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2804, TE[b]=7.3) | | | | Placebo (N[a]=2781, TE[b]=6.4) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Nervous system disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Pregnancy, puerperium and perinatal conditions | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Abortion spontaneous | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Psychiatric disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Renal and urinary disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.6) |
| Reproductive system and breast disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Respiratory, thoracic and mediastinal disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Vascular disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |
| Hypertension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:16)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ser_age_6m_saf

## 14.121. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 24 | 1.1 (0.7, 1.6) | 4.2 | (2.7, 6.2) | 21 | 0.9 (0.6, 1.4) | 4.3 | (2.7, 6.6) |
| Cardiac disorders | 4 | 0.2 (0.0, 0.5) | 0.7 | (0.2, 1.8) | 3 | 0.1 (0.0, 0.4) | 0.6 | (0.1, 1.8) |
| Acute myocardial infarction | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Atrial fibrillation | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Cardiac failure | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pericarditis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Endocrine disorders | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Goitre | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Gastrointestinal disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| General disorders and administration site conditions | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Chest discomfort | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Immune system disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Food allergy | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Infections and infestations | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Appendicitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Appendicitis perforated | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Device related infection | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Diverticulitis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Empyema | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Salmonellosis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Sepsis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Urinary tract infection | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Injury, poisoning and procedural complications | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Hip fracture | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Investigations | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |

## 14.121. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | | Placebo (N[a]=2239, TE[b]=4.9) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Hepatic enzyme increased | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Musculoskeletal and connective tissue disorders | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Back pain | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.0) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Prostate cancer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Nervous system disorders | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Syncope | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Renal and urinary disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.3) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Renal cyst | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 5 | 0.2 (0.1, 0.5) | 1.0 | (0.3, 2.4) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.8) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pleural effusion | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.5) |
| Respiratory failure | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.1) |

## 14.121. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Age Group, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2251, TE[b]=5.8) | | | Placebo (N[a]=2239, TE[b]=4.9) | | |
| System Organ Class Preferred Term | n[c] % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:16)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ser_age_6m_saf

## 14.122. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Male

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2443, TE[b]=6.2) | | | | Placebo (N[a]=2500, TE[b]=5.7) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 21 | 0.9 (0.5, 1.3) | 3.4 | (2.1, 5.1) | 19 | 0.8 (0.5, 1.2) | 3.4 | (2.0, 5.2) |
| Cardiac disorders | 4 | 0.2 (0.0, 0.4) | 0.6 | (0.2, 1.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Acute myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Atrial fibrillation | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Tachycardia | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Endocrine disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Goitre | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Gastrointestinal disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Gastric fistula | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| General disorders and administration site conditions | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Chest discomfort | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Chest pain | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Infections and infestations | 5 | 0.2 (0.1, 0.5) | 0.8 | (0.3, 1.9) | 4 | 0.2 (0.0, 0.4) | 0.7 | (0.2, 1.8) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Appendicitis | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Device related infection | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Salmonellosis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Sepsis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Urinary tract infection | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Injury, poisoning and procedural complications | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hip fracture | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Humerus fracture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Ligament rupture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |

## 14.122. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Male

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2443, TE[b]=6.2) | | | | Placebo (N[a]=2500, TE[b]=5.7) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Musculoskeletal and connective tissue disorders | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Back pain | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.4) | 5 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 2.1) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Prostate cancer | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Nervous system disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 3 | 0.1 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Cerebrovascular accident | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Syncope | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.2) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Renal and urinary disorders | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.9) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Respiratory, thoracic and mediastinal disorders | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 4 | 0.2 (0.0, 0.4) | 0.7 | (0.2, 1.8) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Respiratory failure | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Vascular disorders | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hypertension | 0 | 0.0 (0.0, 0.2) | 0.0 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |

## 14.122. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Male

| | Vaccine Group (as Administered) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2443, TE[b]=6.2) | | | Placebo (N[a]=2500, TE[b]=5.7) | | |
| System Organ Class Preferred Term | n[c] % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ser_sex_6m.sas

## 14.123. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | | Placebo (N[a]=2520, TE[b]=5.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 18 | 0.7 (0.4, 1.1) | 2.6 | (1.6, 4.2) | 16 | 0.6 (0.4, 1.0) | 2.8 | (1.6, 4.6) |
| Cardiac disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Acute myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Atrial fibrillation | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Cardiac failure | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Myocardial infarction | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pericarditis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Endocrine disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Goitre | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Gastrointestinal disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 2 | 0.1 (0.0, 0.3) | 0.4 | (0.0, 1.3) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Hepatobiliary disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Bile duct stone | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Immune system disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Food allergy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Infections and infestations | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.3) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Appendicitis perforated | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Diverticulitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Empyema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Septic shock | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Injury, poisoning and procedural complications | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Stoma complication | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Investigations | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Hepatic enzyme increased | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Musculoskeletal and connective tissue disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Back pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |

## 14.123. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | | Placebo (N[a]=2520, TE[b]=5.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 3 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.3) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Nervous system disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Pregnancy, puerperium and perinatal conditions | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Abortion spontaneous | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Psychiatric disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Renal and urinary disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Renal cyst | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Reproductive system and breast disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 3 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.6) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.7) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pleural effusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 1.0) |

## 14.123. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Sex, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Sex: Female

| | Vaccine Group (as Administered) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2612, TE[b]=6.8) | | | Placebo (N[a]=2520, TE[b]=5.6) | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ser_sex_6m.saf

## 14.124. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 34 | 0.9 (0.6, 1.2) | 3.4 | (2.3, 4.7) | 28 | 0.7 (0.5, 1.0) | 3.2 | (2.1, 4.6) |
| Cardiac disorders | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Acute myocardial infarction | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Atrial fibrillation | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cardiac failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Tachycardia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Endocrine disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Goitre | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Gastrointestinal disorders | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Gastric fistula | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| General disorders and administration site conditions | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Chest discomfort | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hepatobiliary disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Bile duct stone | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Immune system disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Food allergy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Infections and infestations | 7 | 0.2 (0.1, 0.4) | 0.7 | (0.3, 1.4) | 5 | 0.1 (0.0, 0.3) | 0.6 | (0.2, 1.3) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Appendicitis | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Appendicitis perforated | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Device related infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Diverticulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Empyema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Salmonellosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Sepsis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.124. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Urinary tract infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Injury, poisoning and procedural complications | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hip fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Humerus fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ligament rupture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Investigations | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hepatic enzyme increased | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Musculoskeletal and connective tissue disorders | 4 | 0.1 (0.0, 0.3) | 0.4 | (0.1, 1.0) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Back pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) | 5 | 0.1 (0.0, 0.3) | 0.6 | (0.2, 1.3) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Prostate cancer | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nervous system disorders | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Syncope | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |

## 14.124. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: White

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=3986, TE[b]=10.1) | | | | Placebo (N[a]=3993, TE[b]=8.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pregnancy, puerperium and perinatal conditions | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Abortion spontaneous | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Renal and urinary disorders | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Nephrolithiasis | 2 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Renal cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 5 | 0.1 (0.0, 0.3) | 0.6 | (0.2, 1.3) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pleural effusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 1.0) |
| Vascular disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Hypertension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

Note: MedDRA (v24.1) coding dictionary applied.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_bBIA/C4591031_A_SBLA/adae_s131_ser_race_6m_saf

## 14.125. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: Black or African American

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=457, TE[b]=1.4) | | | | Placebo (N[a]=447, TE[b]=1.1) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 2 | 0.4 (0.1, 1.6) | 1.5 | (0.2, 5.3) | 3 | 0.7 (0.1, 1.9) | 2.7 | (0.6, 7.9) |
| Cardiac disorders | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Myocardial infarction | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Pericarditis | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Infections and infestations | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Prostate cancer | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Nervous system disorders | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Cerebrovascular accident | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Syncope | 1 | 0.2 (0.0, 1.2) | 0.7 | (0.0, 4.1) | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 3.3) |
| Respiratory, thoracic and mediastinal disorders | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 2 | 0.4 (0.1, 1.6) | 1.8 | (0.2, 6.5) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |
| Respiratory failure | 0 | 0.0 (0.0, 0.8) | 0.0 | (0.0, 2.7) | 1 | 0.2 (0.0, 1.2) | 0.9 | (0.0, 5.0) |

Note: MedDRA (v24.1) coding dictionary applied.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: /nda2_ubBIA/C4591031_A_SBLA/adae_s131_ser_race_6m_saf

## 14.126. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Race, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Race: All Others

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=612, TE[b]=1.6) | | | | Placebo (N[a]=580, TE[b]=1.4) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 3 | 0.5 (0.1, 1.4) | 1.9 | (0.4, 5.4) | 4 | 0.7 (0.2, 1.8) | 2.9 | (0.8, 7.5) |
| Infections and infestations | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Cholangitis infective | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Septic shock | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Injury, poisoning and procedural complications | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Stoma complication | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Nervous system disorders | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Pregnancy, puerperium and perinatal conditions | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Abortion spontaneous | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Psychiatric disorders | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Suicidal ideation | 1 | 0.2 (0.0, 0.9) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.7) |
| Reproductive system and breast disorders | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |
| Adenomyosis | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.7 | (0.0, 4.1) |

Note: MedDRA (v24.1) coding dictionary applied.
Note: All Others = American Indian or Alaska native, Asian, Native Hawaiian or other Pacific Islander, multiracial, and not reported race categories.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ser_race_6m_saf

## 14.127. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Hispanic/Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=757, TE[b]=2.0) | | | | Placebo (N[a]=749, TE[b]=1.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 3 | 0.4 (0.1, 1.2) | 1.5 | (0.3, 4.4) | 6 | 0.8 (0.3, 1.7) | 3.4 | (1.2, 7.3) |
| Cardiac disorders | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Acute myocardial infarction | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Endocrine disorders | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Goitre | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| General disorders and administration site conditions | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Hepatobiliary disorders | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Bile duct stone | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Immune system disorders | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Food allergy | 1 | 0.1 (0.0, 0.7) | 0.5 | (0.0, 2.8) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Infections and infestations | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Pneumonia | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Nervous system disorders | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Renal and urinary disorders | 2 | 0.3 (0.0, 1.0) | 1.0 | (0.1, 3.6) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Nephrolithiasis | 2 | 0.3 (0.0, 1.0) | 1.0 | (0.1, 3.6) | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 2.1) |
| Respiratory, thoracic and mediastinal disorders | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Vascular disorders | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |
| Hypertension | 0 | 0.0 (0.0, 0.5) | 0.0 | (0.0, 1.8) | 1 | 0.1 (0.0, 0.7) | 0.6 | (0.0, 3.1) |

## 14.127. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Hispanic/Latino

| | Vaccine Group (as Administered) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=757, TE[b]=2.0) | | | Placebo (N[a]=749, TE[b]=1.8) | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ser_ethnic_6m_saf

## 14.128. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 36 | 0.8 (0.6, 1.2) | 3.3 | (2.3, 4.5) | 29 | 0.7 (0.5, 1.0) | 3.1 | (2.0, 4.4) |
| Cardiac disorders | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.1) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Acute myocardial infarction | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Atrial fibrillation | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cardiac failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pericarditis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tachycardia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Endocrine disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Goitre | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Gastrointestinal disorders | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Gastric fistula | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| General disorders and administration site conditions | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Chest discomfort | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Infections and infestations | 8 | 0.2 (0.1, 0.4) | 0.7 | (0.3, 1.4) | 6 | 0.1 (0.1, 0.3) | 0.6 | (0.2, 1.4) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Appendicitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Appendicitis perforated | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Device related infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Diverticulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Empyema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Salmonellosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Sepsis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Septic shock | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |

## 14.128. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Urinary tract infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Injury, poisoning and procedural complications | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hip fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Humerus fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ligament rupture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Stoma complication | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Investigations | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hepatic enzyme increased | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Musculoskeletal and connective tissue disorders | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Back pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 6 | 0.1 (0.1, 0.3) | 0.5 | (0.2, 1.2) | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Prostate cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nervous system disorders | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Syncope | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |

## 14.128. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Non-Hispanic/Non-Latino

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4286, TE[b]=11.0) | | | | Placebo (N[a]=4263, TE[b]=9.5) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pregnancy, puerperium and perinatal conditions | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Abortion spontaneous | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Psychiatric disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Renal and urinary disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Renal cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Reproductive system and breast disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 6 | 0.1 (0.1, 0.3) | 0.6 | (0.2, 1.4) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pleural effusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Respiratory failure | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ser_ethnic_6m_saf

## 14.129. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Ethnicity, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Ethnicity: Not Reported

| | Vaccine Group (as Administered) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=12, TE[b]=0.0) | | | Placebo (N[a]=8, TE[b]=0.0) | | |
| System Organ Class<br>Preferred Term | n[c] % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 0 0.0 (0.0, 26.5) | 0.0 | (0.0, 149.7) | 0 0.0 (0.0, 36.9) | 0.0 | (0.0, 284.3) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_set_ethnic_6m_saf

## 14.130. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: Brazil

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=580, TE[b]=1.6) | | | | Placebo (N[a]=582, TE[b]=1.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 5 | 0.9 (0.3, 2.0) | 3.1 | (1.0, 7.2) | 5 | 0.9 (0.3, 2.0) | 3.1 | (1.0, 7.3) |
| Endocrine disorders | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Goitre | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Gastrointestinal disorders | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Gastric fistula | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| General disorders and administration site conditions | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Hepatobiliary disorders | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Bile duct stone | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Infections and infestations | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Abdominal sepsis | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Injury, poisoning and procedural complications | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Ligament rupture | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.4) | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) |
| Nervous system disorders | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Pregnancy, puerperium and perinatal conditions | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Abortion spontaneous | 2 | 0.3 (0.0, 1.2) | 1.2 | (0.1, 4.5) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Vascular disorders | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |
| Hypertension | 0 | 0.0 (0.0, 0.6) | 0.0 | (0.0, 2.3) | 1 | 0.2 (0.0, 1.0) | 0.6 | (0.0, 3.5) |

## 14.130. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: Brazil

| | Vaccine Group (as Administered) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=580, TE[b]=1.6) | | | Placebo (N[a]=582, TE[b]=1.6) | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ser_cntry_6m_saf

## 14.131. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: South Africa

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=123, TE[b]=0.4) | | | | Placebo (N[a]=128, TE[b]=0.3) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 0 | 0.0 (0.0, 3.0) | 0.0 | (0.0, 9.1) | 0 | 0.0 (0.0, 2.8) | 0.0 | (0.0, 10.7) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s13_ser_cntry_6m_saf

## 14.132. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 34 | 0.8 (0.5, 1.1) | 3.1 | (2.1, 4.3) | 30 | 0.7 (0.5, 1.0) | 3.2 | (2.2, 4.6) |
| Cardiac disorders | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.1, 1.1) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.1) |
| Acute myocardial infarction | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Atrial fibrillation | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Cardiac failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pericarditis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Tachycardia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Ventricular extrasystoles | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Endocrine disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Goitre | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Gastrointestinal disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| General disorders and administration site conditions | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Chest discomfort | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Immune system disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Food allergy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Infections and infestations | 7 | 0.2 (0.1, 0.3) | 0.6 | (0.3, 1.3) | 6 | 0.1 (0.1, 0.3) | 0.6 | (0.2, 1.4) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Appendicitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Appendicitis perforated | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Device related infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Diverticulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Empyema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Salmonellosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Sepsis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Septic shock | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Urinary tract infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.132. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Injury, poisoning and procedural complications | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hip fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Humerus fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Stoma complication | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Investigations | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hepatic enzyme increased | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Musculoskeletal and connective tissue disorders | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Back pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 6 | 0.1 (0.1, 0.3) | 0.5 | (0.2, 1.2) | 5 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.2) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Lung carcinoma cell type unspecified stage II | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Prostate cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Nervous system disorders | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 0.9) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Syncope | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

## 14.132. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Country, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Country: USA

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4352, TE[b]=11.0) | | | | Placebo (N[a]=4310, TE[b]=9.3) | | | |
| | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Psychiatric disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Renal and urinary disorders | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.8) |
| Nephrolithiasis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Renal cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Reproductive system and breast disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 7 | 0.2 (0.1, 0.3) | 0.7 | (0.3, 1.5) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.4) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pleural effusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.9) |
| Respiratory failure | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.6) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:37)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_bBIA/C4591031_A_SBLA/adae_s131_ser_cntry_6m_saf

## 14.133. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Positive

| | Vaccine Group (as Administered) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=283, TE[b]=0.8) | | | Placebo (N[a]=259, TE[b]=0.6) | | |
| System Organ Class<br>Preferred Term | n[c] % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 0 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 3 1.2 (0.2, 3.3) | 4.7 | (1.0, 13.7) |
| Cardiac disorders | 0 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 2 0.8 (0.1, 2.8) | 3.1 | (0.4, 11.3) |
| Myocardial infarction | 0 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Pericarditis | 0 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Ventricular extrasystoles | 0 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |
| Lung carcinoma cell type unspecified stage II | 0 0.0 (0.0, 1.3) | 0.0 | (0.0, 4.4) | 1 0.4 (0.0, 2.1) | 1.6 | (0.0, 8.7) |

Note: MedDRA (v24.1) coding dictionary applied.
Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 01APR2022 (06:02)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_subBIA/C4591031_A_SBLA/adae_s131_ser_base_6m_saf

## 14.134. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 39 | 0.8 (0.6, 1.1) | 3.2 | (2.3, 4.4) | 32 | 0.7 (0.5, 0.9) | 3.0 | (2.1, 4.2) |
| Cardiac disorders | 5 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Acute myocardial infarction | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Atrial fibrillation | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Cardiac failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Coronary artery disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Tachycardia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Endocrine disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Goitre | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Gastrointestinal disorders | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Gastric fistula | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Upper gastrointestinal haemorrhage | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| General disorders and administration site conditions | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Chest discomfort | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Non-cardiac chest pain | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hepatobiliary disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Bile duct stone | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Immune system disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Food allergy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Infections and infestations | 8 | 0.2 (0.1, 0.3) | 0.7 | (0.3, 1.3) | 7 | 0.1 (0.1, 0.3) | 0.7 | (0.3, 1.4) |
| Abdominal abscess | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abdominal sepsis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Acquired immunodeficiency syndrome | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Appendicitis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Appendicitis perforated | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| COVID-19 pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cholangitis infective | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Device related infection | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Diverticulitis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Empyema | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

## 14.134. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Pneumocystis jirovecii pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pneumonia | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Salmonellosis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Sepsis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Septic shock | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Urinary tract infection | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Injury, poisoning and procedural complications | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Acetabulum fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hip fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Humerus fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ligament rupture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pelvic fracture | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Stoma complication | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Thoracic vertebral fracture | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Investigations | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hepatic enzyme increased | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Musculoskeletal and connective tissue disorders | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Back pain | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intervertebral disc protrusion | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Intervertebral disc space narrowing | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Osteoarthritis | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Spinal osteoarthritis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 6 | 0.1 (0.0, 0.3) | 0.5 | (0.2, 1.1) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Acute lymphocytic leukaemia | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Follicular lymphoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Invasive ductal breast carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Ovarian cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Pancreatic carcinoma | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pancreatic carcinoma metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Prostate cancer | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

## 14.134. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | | Placebo (N[a]=4754, TE[b]=10.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Renal cell carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Nervous system disorders | 4 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) | 4 | 0.1 (0.0, 0.2) | 0.4 | (0.1, 1.0) |
| Cerebral venous thrombosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Cerebrovascular accident | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Intracranial aneurysm | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Syncope | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Toxic encephalopathy | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Toxic leukoencephalopathy | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pregnancy, puerperium and perinatal conditions | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Abortion spontaneous | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Psychiatric disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Suicidal ideation | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Renal and urinary disorders | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.1, 0.7) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Acute kidney injury | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| Nephrolithiasis | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Renal cyst | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Reproductive system and breast disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Adenomyosis | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 7 | 0.1 (0.1, 0.3) | 0.7 | (0.3, 1.4) |
| Acute respiratory failure | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) |
| Chronic obstructive pulmonary disease | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Dyspnoea | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pleural effusion | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Pulmonary embolism | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 3 | 0.1 (0.0, 0.2) | 0.3 | (0.1, 0.8) |
| Respiratory failure | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Vascular disorders | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |
| Hypertension | 0 | 0.0 (0.0, 0.1) | 0.0 | (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.5) |

## 14.134. Incidence Rates of at Least 1 Serious Adverse Event From Booster Vaccination to Unblinding Date, by Baseline SARS-CoV-2 Status, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population Baseline SARS-CoV-2 Status: Negative

| | Vaccine Group (as Administered) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4765, TE[b]=12.2) | | | Placebo (N[a]=4754, TE[b]=10.6) | | |
| System Organ Class Preferred Term | n[c] % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) | n[c] % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
Abbreviations: N-binding = SARS-CoV-2 nucleoprotein–binding; NAAT = nucleic acid amplification test; SARS-CoV-2 = severe acute respiratory syndrome coronavirus 2.
Note: Participants whose baseline SARS-CoV-2 status cannot be determined because of missing N-binding antibody or NAAT at Visit 1 were not included in the analysis.
Note: Positive = positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. Negative = negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 01APR2022 (06:02)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_ser_base_6m_saf

## 14.135. Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2496, TE[b]=7.7) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 17 | 0.7 (0.4, 1.1) | 2.2 | (1.3, 3.5) |
| Blood and lymphatic system disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Sickle cell anaemia with crisis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Cardiac disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 0.9) |
| Acute myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Myocardial infarction | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Gastrointestinal disorders | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.1) |
| Gastrointestinal haemorrhage | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Intestinal perforation | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Pancreatic pseudocyst | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Pancreatitis acute | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| General disorders and administration site conditions | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Non-cardiac chest pain | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Infections and infestations | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.1) |
| Appendicitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Gastroenteritis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Lyme disease | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Peritonitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Musculoskeletal and connective tissue disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Arthralgia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 3 | 0.1 (0.0, 0.4) | 0.4 | (0.1, 1.1) |
| Brain neoplasm | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Meningioma | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Nervous system neoplasm | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Nervous system disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 0.9) |
| Cerebral haemorrhage | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Seizure | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Psychiatric disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Bipolar disorder | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Renal and urinary disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Nephrolithiasis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |

## 14.135. Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2496, TE[b]=7.7) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Negative pressure pulmonary oedema | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Vascular disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |
| Shock haemorrhagic | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.7) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from unblinding date to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:32)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_sae_age_bnt_ol_saf

## 14.136. Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1993, TE[b]=6.5) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 19 | 1.0 (0.6, 1.5) | 2.9 | (1.8, 4.6) |
| Cardiac disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Atrial fibrillation | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Gastrointestinal disorders | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.4) |
| Colitis | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Hiatus hernia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Lower gastrointestinal haemorrhage | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| General disorders and administration site conditions | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.1) |
| Chest pain | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Death | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Infections and infestations | 4 | 0.2 (0.1, 0.5) | 0.6 | (0.2, 1.6) |
| Cellulitis | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Infection | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Liver abscess | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Osteomyelitis | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Injury, poisoning and procedural complications | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.4) |
| Clavicle fracture | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Craniocerebral injury | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Subdural haematoma | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Metabolism and nutrition disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Hypervolaemia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 4 | 0.2 (0.1, 0.5) | 0.6 | (0.2, 1.6) |
| Breast cancer | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Invasive ductal breast carcinoma | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Prostate cancer | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Uterine cancer | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Nervous system disorders | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.1) |
| Cerebrovascular accident | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Syncope | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| Renal and urinary disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |
| End stage renal disease | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 0.9) |

## 14.136. Incidence Rates of at Least 1 Serious Adverse Event From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1993, TE[b]=6.5) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from unblinding date to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:14) Source Data: adae Table Generation: 14MAR2022 (23:32)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_sae_age_bnt_ol_saf

## 14.137. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2770)<br>n[b] (%) | (95% CI[c]) |
|---|---|---|
| Any event | 28 (1.0) | (0.7, 1.5) |
| Blood and lymphatic system disorders | 1 (0.0) | (0.0, 0.2) |
| Sickle cell anaemia with crisis | 1 (0.0) | (0.0, 0.2) |
| Cardiac disorders | 2 (0.1) | (0.0, 0.3) |
| Acute myocardial infarction | 1 (0.0) | (0.0, 0.2) |
| Atrial fibrillation | 0 | (0.0, 0.1) |
| Cardiac failure | 0 | (0.0, 0.1) |
| Myocardial infarction | 0 | (0.0, 0.1) |
| Tachycardia | 1 (0.0) | (0.0, 0.2) |
| Endocrine disorders | 1 (0.0) | (0.0, 0.2) |
| Goitre | 1 (0.0) | (0.0, 0.2) |
| Gastrointestinal disorders | 3 (0.1) | (0.0, 0.3) |
| Colitis | 0 | (0.0, 0.1) |
| Gastric fistula | 1 (0.0) | (0.0, 0.2) |
| Hiatus hernia | 0 | (0.0, 0.1) |
| Intestinal perforation | 1 (0.0) | (0.0, 0.2) |
| Lower gastrointestinal haemorrhage | 0 | (0.0, 0.1) |
| Pancreatic pseudocyst | 1 (0.0) | (0.0, 0.2) |
| Pancreatitis acute | 1 (0.0) | (0.0, 0.2) |
| Small intestinal obstruction | 0 | (0.0, 0.1) |
| General disorders and administration site conditions | 1 (0.0) | (0.0, 0.2) |
| Chest discomfort | 0 | (0.0, 0.1) |
| Death | 0 | (0.0, 0.1) |
| Non-cardiac chest pain | 1 (0.0) | (0.0, 0.2) |
| Immune system disorders | 0 | (0.0, 0.1) |
| Food allergy | 0 | (0.0, 0.1) |
| Infections and infestations | 6 (0.2) | (0.1, 0.5) |
| Appendicitis | 2 (0.1) | (0.0, 0.3) |
| Abdominal sepsis | 1 (0.0) | (0.0, 0.2) |
| Appendicitis perforated | 0 | (0.0, 0.1) |
| Cellulitis | 0 | (0.0, 0.1) |
| Cholangitis infective | 1 (0.0) | (0.0, 0.2) |

**14.137. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2770)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Device related infection | 0 | (0.0, 0.1) |
| Diverticulitis | 0 | (0.0, 0.1) |
| Gastroenteritis | 1 (0.0) | (0.0, 0.2) |
| Liver abscess | 0 | (0.0, 0.1) |
| Lyme disease | 1 (0.0) | (0.0, 0.2) |
| Osteomyelitis | 0 | (0.0, 0.1) |
| Peritonitis | 1 (0.0) | (0.0, 0.2) |
| Salmonellosis | 0 | (0.0, 0.1) |
| Septic shock | 1 (0.0) | (0.0, 0.2) |
| Injury, poisoning and procedural complications | 3 (0.1) | (0.0, 0.3) |
| Acetabulum fracture | 0 | (0.0, 0.1) |
| Clavicle fracture | 0 | (0.0, 0.1) |
| Craniocerebral injury | 0 | (0.0, 0.1) |
| Humerus fracture | 1 (0.0) | (0.0, 0.2) |
| Ligament rupture | 1 (0.0) | (0.0, 0.2) |
| Pelvic fracture | 0 | (0.0, 0.1) |
| Stoma complication | 1 (0.0) | (0.0, 0.2) |
| Subdural haematoma | 0 | (0.0, 0.1) |
| Investigations | 1 (0.0) | (0.0, 0.2) |
| Hepatic enzyme increased | 1 (0.0) | (0.0, 0.2) |
| Metabolism and nutrition disorders | 0 | (0.0, 0.1) |
| Hypervolaemia | 0 | (0.0, 0.1) |
| Musculoskeletal and connective tissue disorders | 2 (0.1) | (0.0, 0.3) |
| Arthralgia | 1 (0.0) | (0.0, 0.2) |
| Back pain | 1 (0.0) | (0.0, 0.2) |
| Intervertebral disc protrusion | 0 | (0.0, 0.1) |
| Intervertebral disc space narrowing | 0 | (0.0, 0.1) |
| Osteoarthritis | 0 | (0.0, 0.1) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 4 (0.1) | (0.0, 0.4) |
| Invasive ductal breast carcinoma | 0 | (0.0, 0.1) |
| Prostate cancer | 0 | (0.0, 0.1) |
| Acute lymphocytic leukaemia | 1 (0.0) | (0.0, 0.2) |
| Brain neoplasm | 1 (0.0) | (0.0, 0.2) |
| Breast cancer | 0 | (0.0, 0.1) |
| Follicular lymphoma | 0 | (0.0, 0.1) |

## 14.137. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: 16-55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg)<br>(N[a]=2770)<br>n[b] (%) | <br><br><br>(95% CI[c]) |
|---|---|---|
| Meningioma | 1 (0.0) | (0.0, 0.2) |
| Nervous system neoplasm | 1 (0.0) | (0.0, 0.2) |
| Ovarian cancer | 0 | (0.0, 0.1) |
| Renal cell carcinoma | 0 | (0.0, 0.1) |
| Uterine cancer | 0 | (0.0, 0.1) |
| Nervous system disorders | 2 (0.1) | (0.0, 0.3) |
| Syncope | 0 | (0.0, 0.1) |
| Cerebrovascular accident | 0 | (0.0, 0.1) |
| Cerebral haemorrhage | 1 (0.0) | (0.0, 0.2) |
| Toxic encephalopathy | 1 (0.0) | (0.0, 0.2) |
| Pregnancy, puerperium and perinatal conditions | 2 (0.1) | (0.0, 0.3) |
| Abortion spontaneous | 2 (0.1) | (0.0, 0.3) |
| Psychiatric disorders | 1 (0.0) | (0.0, 0.2) |
| Suicidal ideation | 1 (0.0) | (0.0, 0.2) |
| Renal and urinary disorders | 2 (0.1) | (0.0, 0.3) |
| Nephrolithiasis | 2 (0.1) | (0.0, 0.3) |
| End stage renal disease | 0 | (0.0, 0.1) |
| Renal cyst | 0 | (0.0, 0.1) |
| Respiratory, thoracic and mediastinal disorders | 0 | (0.0, 0.1) |
| Acute respiratory failure | 0 | (0.0, 0.1) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:02)
(Data cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_ser_all_6m_3k_age_saf

## 14.138. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2230)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Any event | 39 (1.7) | (1.2, 2.4) |
| Blood and lymphatic system disorders | 0 | (0.0, 0.2) |
| Sickle cell anaemia with crisis | 0 | (0.0, 0.2) |
| Cardiac disorders | 5 (0.2) | (0.1, 0.5) |
| Acute myocardial infarction | 2 (0.1) | (0.0, 0.3) |
| Atrial fibrillation | 3 (0.1) | (0.0, 0.4) |
| Cardiac failure | 1 (0.0) | (0.0, 0.2) |
| Myocardial infarction | 1 (0.0) | (0.0, 0.2) |
| Tachycardia | 0 | (0.0, 0.2) |
| Endocrine disorders | 0 | (0.0, 0.2) |
| Goitre | 0 | (0.0, 0.2) |
| Gastrointestinal disorders | 4 (0.2) | (0.0, 0.5) |
| Colitis | 1 (0.0) | (0.0, 0.2) |
| Gastric fistula | 0 | (0.0, 0.2) |
| Hiatus hernia | 1 (0.0) | (0.0, 0.2) |
| Intestinal perforation | 0 | (0.0, 0.2) |
| Lower gastrointestinal haemorrhage | 1 (0.0) | (0.0, 0.2) |
| Pancreatic pseudocyst | 0 | (0.0, 0.2) |
| Pancreatitis acute | 0 | (0.0, 0.2) |
| Small intestinal obstruction | 1 (0.0) | (0.0, 0.2) |
| General disorders and administration site conditions | 2 (0.1) | (0.0, 0.3) |
| Chest discomfort | 1 (0.0) | (0.0, 0.2) |
| Death | 1 (0.0) | (0.0, 0.2) |
| Non-cardiac chest pain | 0 | (0.0, 0.2) |
| Immune system disorders | 1 (0.0) | (0.0, 0.2) |
| Food allergy | 1 (0.0) | (0.0, 0.2) |
| Infections and infestations | 7 (0.3) | (0.1, 0.6) |
| Appendicitis | 1 (0.0) | (0.0, 0.2) |
| Abdominal sepsis | 0 | (0.0, 0.2) |
| Appendicitis perforated | 1 (0.0) | (0.0, 0.2) |
| Cellulitis | 1 (0.0) | (0.0, 0.2) |
| Cholangitis infective | 0 | (0.0, 0.2) |
| Device related infection | 1 (0.0) | (0.0, 0.2) |

**14.138. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years**

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2230)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Diverticulitis | 1 (0.0) | (0.0, 0.2) |
| Gastroenteritis | 0 | (0.0, 0.2) |
| Liver abscess | 1 (0.0) | (0.0, 0.2) |
| Lyme disease | 0 | (0.0, 0.2) |
| Osteomyelitis | 1 (0.0) | (0.0, 0.2) |
| Peritonitis | 0 | (0.0, 0.2) |
| Salmonellosis | 1 (0.0) | (0.0, 0.2) |
| Septic shock | 0 | (0.0, 0.2) |
| Injury, poisoning and procedural complications | 4 (0.2) | (0.0, 0.5) |
| Acetabulum fracture | 1 (0.0) | (0.0, 0.2) |
| Clavicle fracture | 1 (0.0) | (0.0, 0.2) |
| Craniocerebral injury | 1 (0.0) | (0.0, 0.2) |
| Humerus fracture | 0 | (0.0, 0.2) |
| Ligament rupture | 0 | (0.0, 0.2) |
| Pelvic fracture | 1 (0.0) | (0.0, 0.2) |
| Stoma complication | 0 | (0.0, 0.2) |
| Subdural haematoma | 1 (0.0) | (0.0, 0.2) |
| Investigations | 1 (0.0) | (0.0, 0.2) |
| Hepatic enzyme increased | 1 (0.0) | (0.0, 0.2) |
| Metabolism and nutrition disorders | 1 (0.0) | (0.0, 0.2) |
| Hypervolaemia | 1 (0.0) | (0.0, 0.2) |
| Musculoskeletal and connective tissue disorders | 3 (0.1) | (0.0, 0.4) |
| Arthralgia | 0 | (0.0, 0.2) |
| Back pain | 0 | (0.0, 0.2) |
| Intervertebral disc protrusion | 1 (0.0) | (0.0, 0.2) |
| Intervertebral disc space narrowing | 1 (0.0) | (0.0, 0.2) |
| Osteoarthritis | 1 (0.0) | (0.0, 0.2) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 9 (0.4) | (0.2, 0.8) |
| Invasive ductal breast carcinoma | 2 (0.1) | (0.0, 0.3) |
| Prostate cancer | 2 (0.1) | (0.0, 0.3) |
| Acute lymphocytic leukaemia | 0 | (0.0, 0.2) |
| Brain neoplasm | 0 | (0.0, 0.2) |
| Breast cancer | 1 (0.0) | (0.0, 0.2) |
| Follicular lymphoma | 1 (0.0) | (0.0, 0.2) |
| Meningioma | 0 | (0.0, 0.2) |

## 14.138. Number (%) of Participants Reporting at Least 1 Serious Adverse Event From Booster Vaccination to 6 Months After Booster Vaccination, by System Organ Class and Preferred Term, by Age Group – Participants With at Least 6 Months of Follow-Up Time After Booster Vaccination – Participants Who Originally Received BNT162b2 – Safety Population Age Group: >55 Years

| System Organ Class<br>Preferred Term | Vaccine Group (as Administered)<br>BNT162b2 (30 µg) (N[a]=2230)<br>n[b] (%) | <br><br>(95% CI[c]) |
|---|---|---|
| Nervous system neoplasm | 0 | (0.0, 0.2) |
| Ovarian cancer | 1 (0.0) | (0.0, 0.2) |
| Renal cell carcinoma | 1 (0.0) | (0.0, 0.2) |
| Uterine cancer | 1 (0.0) | (0.0, 0.2) |
| Nervous system disorders | 5 (0.2) | (0.1, 0.5) |
| Syncope | 3 (0.1) | (0.0, 0.4) |
| Cerebrovascular accident | 2 (0.1) | (0.0, 0.3) |
| Cerebral haemorrhage | 0 | (0.0, 0.2) |
| Toxic encephalopathy | 0 | (0.0, 0.2) |
| Pregnancy, puerperium and perinatal conditions | 0 | (0.0, 0.2) |
| Abortion spontaneous | 0 | (0.0, 0.2) |
| Psychiatric disorders | 0 | (0.0, 0.2) |
| Suicidal ideation | 0 | (0.0, 0.2) |
| Renal and urinary disorders | 3 (0.1) | (0.0, 0.4) |
| Nephrolithiasis | 1 (0.0) | (0.0, 0.2) |
| End stage renal disease | 1 (0.0) | (0.0, 0.2) |
| Renal cyst | 1 (0.0) | (0.0, 0.2) |
| Respiratory, thoracic and mediastinal disorders | 1 (0.0) | (0.0, 0.2) |
| Acute respiratory failure | 1 (0.0) | (0.0, 0.2) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
c. Exact 2-sided CI based on the Clopper and Pearson method.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:02)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_bBIA/C4591031_A_SBLA/adae_s130_ser_all_6m_3k_age_saf

## 14.139. Incidence Rates of at Least 1 Serious Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: 16-55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=2449, TE[b]=6.8) | | | |
| System Organ Class Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 6 | 0.2 (0.1, 0.5) | 0.9 | (0.3, 1.9) |
| Gastrointestinal disorders | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Pancreatitis acute | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Small intestinal obstruction | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Infections and infestations | 2 | 0.1 (0.0, 0.3) | 0.3 | (0.0, 1.1) |
| Diverticulitis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Pneumonia | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Injury, poisoning and procedural complications | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Multiple injuries | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Road traffic accident | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Vascular disorders | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |
| Deep vein thrombosis | 1 | 0.0 (0.0, 0.2) | 0.1 | (0.0, 0.8) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:10)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBJA/C4591031_A_SBLA/adae_s130_cut_sae_age_ol_saf

## 14.140. Incidence Rates of at Least 1 Serious Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1947, TE[b]=5.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 13 | 0.7 (0.4, 1.1) | 2.2 | (1.2, 3.8) |
| Cardiac disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Atrial fibrillation | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Gastrointestinal disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Small intestinal obstruction | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| General disorders and administration site conditions | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Death | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Sudden cardiac death | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Infections and infestations | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| COVID-19 pneumonia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Cellulitis | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Urinary tract infection | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Injury, poisoning and procedural complications | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Femur fracture | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Musculoskeletal and connective tissue disorders | 3 | 0.2 (0.0, 0.4) | 0.5 | (0.1, 1.5) |
| Arthralgia | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Osteoarthritis | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 2 | 0.1 (0.0, 0.4) | 0.3 | (0.0, 1.2) |
| Adrenocortical carcinoma | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Biliary neoplasm | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Respiratory, thoracic and mediastinal disorders | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |
| Chronic obstructive pulmonary disease | 1 | 0.1 (0.0, 0.3) | 0.2 | (0.0, 1.0) |

## 14.140. Incidence Rates of at Least 1 Serious Adverse Event From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term, by Age Group – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population Age Group: >55 Years

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=1947, TE[b]=5.8) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (23:10)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_sae_age_ol_saf

## 14.141. Incidence Rates of Participants Withdrawn Because of Adverse Event From Booster Vaccination to Unblinding Date, by System Organ Class and Preferred Term – Blinded Follow-Up Period – Safety Population

| | Vaccine Group (as Administered) | | | | | |
|---|---|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=5055, TE[b]=13.0) | | | Placebo (N[a]=5020, TE[b]=11.3) | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) (95% CI[f]) | n[c] | % (95% CI[d]) | IR (/100 PY[e]) (95% CI[f]) |
| Any event | 0 | 0.0 (0.0, 0.1) | 0.0 (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 (0.0, 0.5) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 0 | 0.0 (0.0, 0.1) | 0.0 (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 (0.0, 0.5) |
| Hepatic cancer metastatic | 0 | 0.0 (0.0, 0.1) | 0.0 (0.0, 0.3) | 1 | 0.0 (0.0, 0.1) | 0.1 (0.0, 0.5) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to the end of blinded follow-up. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 31MAR2022 (12:49)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s131_6m_wd_saf

## 14.142. Incidence Rates of Participants Withdrawn Because of Adverse Events From Unblinding Date to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received BNT162b2 – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4489, TE[b]=14.2) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR[e] (/100 PY[e]) | (95% CI[f]) |
| Any event | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| General disorders and administration site conditions | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Death | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from unblinding date to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (13:12)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_wd_bnt_ol_saf

## 14.143. Incidence Rates of Participants Withdrawn Because of Adverse Events From BNT162b2 Booster Vaccination to the Cutoff Date, by System Organ Class and Preferred Term – Open-Label Follow-Up Period – Participants Who Originally Received Placebo and Then Received BNT162b2 After Unblinding – Safety Population

| | Vaccine Group (as Administered) | | | |
|---|---|---|---|---|
| | BNT162b2 (30 µg) (N[a]=4396, TE[b]=12.6) | | | |
| System Organ Class<br>Preferred Term | n[c] | % (95% CI[d]) | IR (/100 PY[e]) | (95% CI[f]) |
| Any event | 3 | 0.1 (0.0, 0.2) | 0.2 | (0.0, 0.7) |
| General disorders and administration site conditions | 2 | 0.0 (0.0, 0.2) | 0.2 | (0.0, 0.6) |
| Death | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Sudden cardiac death | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |
| Adrenocortical carcinoma | 1 | 0.0 (0.0, 0.1) | 0.1 | (0.0, 0.4) |

Note: MedDRA (v24.1) coding dictionary applied.
a. N = number of participants in the specified group. This value is the denominator for the percentage calculations.
b. TE = total exposure time in 100 person-years (PYs) across all participants in the specified group. Exposure time for a participant is the time from booster vaccination to data cutoff date. This value is the denominator for the incidence rate calculations.
c. n = Number of participants reporting at least 1 occurrence of the specified event. For "any event," n = number of participants reporting at least 1 occurrence of any event.
d. 2-Sided CI based on Clopper-Pearson.
e. Incidence rate (IR) is calculated as number of participants reporting the event/total exposure time in 100 PYs across all participants in the specified group.
f. 2-Sided CI based on Poisson distribution.
PFIZER CONFIDENTIAL SDTM Creation: 07MAR2022 (23:11) Source Data: adae Table Generation: 14MAR2022 (13:12)
(Data Cutoff Date: 08FEB2022, Database Snapshot Date: 03MAR2022) Output File: ./nda2_ubBIA/C4591031_A_SBLA/adae_s130_cut_wd_ol_saf

## SUPPLEMENTAL FIGURES

None.

## PARTICIPANT NARRATIVES

| Primary Reason for Narrative | Participant Number |
|---|---|
| **Death** | |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| **Related Serious Adverse Event** | |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD (also Adverse Event of Clinical Interest) |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| **Safety-Related Participant Withdrawal** | |
| | Participant PPD |
| | Participant PPD |
| **Adverse Event of Clinical Interest** | |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
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| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |
| | Participant PPD |

Participant PPD
Participant PPD
Participant PPD
Participant PPD
Participant PPD

**Bell's Palsy**

Participant PPD

**Appendicitis**

Participant PPD
Participant PPD
Participant PPD
Participant PPD

PPD

Participant PPD
Participant PPD
Participant PPD
Participant PPD

**COVID-19 Case (Severe and/or Multiple)**

Participant PPD
Participant PPD
Participant PPD
Participant PPD
Participant PPD
Participant PPD
Participant PPD
Participant PPD
Participant PPD
Participant PPD
Participant PPD
Participant PPD
Participant PPD
Participant PPD
Participant PPD

| Table of Abbreviations | | |
|---|---|---|
| **Category** | **Abbreviation** | **Text** |
| Action - Participant | N | No action |
| | O | Other |
| | P | Drug withdrawn (study intervention discontinued) |
| | TC | Concomitant drug treatment given |
| | TCN | Concomitant nondrug treatment given |
| | W | Withdrawn from study |
| Toxicity Grade | 1 | Mild |
| | 2 | Moderate |
| | 3 | Severe |
| | 4 | Life-threatening |
| System Organ Class | BLOOD | Blood and lymphatic system disorders |
| | CARD | Cardiac disorders |
| | CONG | Congenital, familial and genetic disorders |
| | EAR | Ear and labyrinth disorders |
| | ENDO | Endocrine disorders |
| | EYE | Eye disorders |
| | GASTR | Gastrointestinal disorders |
| | GENRL | General disorders and administration site conditions |
| | HEPAT | Hepatobiliary disorders |
| | IMMUN | Immune system disorders |
| | INFEC | Infections and infestations |
| | INJ&P | Injury poisoning and procedural complications |
| | INV | Investigations |
| | METAB | Metabolism and nutrition disorders |
| | MUSC | Musculoskeletal and connective tissue disorders |
| | NEOPL | Neoplasms benign, malignant and unspecified (incl cysts and polyps) |
| | NERV | Nervous system disorders |
| | PREG | Pregnancy, puerperium and perinatal conditions |
| | PSYCH | Psychiatric disorders |

| Table of Abbreviations | | |
|---|---|---|
| **Category** | **Abbreviation** | **Text** |
| | RENAL | Renal and urinary disorders |
| | REPRO | Reproductive system and breast disorders |
| | RESP | Respiratory, thoracic and mediastinal disorders |
| | SKIN | Skin and subcutaneous tissue disorders |
| | SOCCI | Social circumstances |
| | SURG | Surgical and medical procedures |
| | VASC | Vascular disorders |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | ≥75 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** |
| 1 | INFEC | Infection | PPD | PPD () | | PPD (105) | | |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 4 | N | Y | Fatal (PPD) | NOT RELATED/OTHER: UNKNOWN | 1 | | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

Reason(s) for Narrative: Death
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| | TREATMENT UNBLINDED | | |
| | OPEN LABEL TREATMENT | | |
| Withdrawn | FOLLOW-UP | PPD | DEATH |

| **Narrative Comment** |
|---|
| Participant PPD, an ≥75-year-old PPD with a pertinent medical history of PPD (since PPD, PPD PPD (since PPD), PPD (since PPD), with a BMI of PPD kg/m$^2$ at baseline, received BNT162b2 on PPD (Day 1).<br><br>Concomitant medications included PPD (since PPD for PPD, PPD (since PPD) for PPD, PPD (since PPD) for PPD, PPD (since PPD for PPD, PPD (since PPD) for PPD, PPD (since PPD) for PPD and PPD (since PPD).<br><br>The participant was diagnosed with an infection (unspecified) on an unknown date in PPD.<br><br>On an unknown date in PPD, the participant had an infection and was taken to the emergency room. The participant's PPD reported that the participant had complications of infection resulting from an anal fissure. On PPD (Day 105), the participant died because of the infection. No autopsy was performed.<br><br>In the opinion of the investigator, there was no reasonable possibility that the infection was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Past |

Reason(s) for Narrative: Death
Participant: PPD; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD; Date of Last Dose: PPD

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | RESP | Pulmonary embolism | PPD | PPD (52) | | PPD (52) | | 1 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 4 | N | Y | Fatal (PPD) | NOT RELATED/OTHER: IDOPATHIC | 1 | 52 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| | TREATMENT UNBLINDED | | |
| | OPEN LABEL TREATMENT | | |
| Withdrawn | FOLLOW-UP | PPD | DEATH |

| **Narrative Comment** |
|---|
| Participant PPD, a 60-year-old PPD with a pertinent medical history of PPD (since PPD), with a BMI of PPD kg/m$^2$ at baseline, received placebo on PPD (Day 1).<br><br>Concomitant medications included PPD (since PPD) for PPD, PPD (since PPD) for PPD, PPD (since PPD for PPD, and PPD (since PPD for PPD<br><br>The participant was diagnosed with a pulmonary embolism on PPD, 51 days after receiving placebo.<br><br>On PPD (Day 52), the site received a message that the participant died because of a pulmonary embolism. No autopsy was performed.<br><br>In the opinion of the investigator, there was no reasonable possibility that the pulmonary embolism was related to the placebo, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History |
|---|
| No Medical History |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (104) | PPD |

| Adverse Events | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** | **Toxicity Grade** | **Action to Participant** | **SAE** |
| 1 | GENRL | Death | PPD | PPD (152) | | PPD (152) | | 1 | 4 | W | Y |

| Adverse Events | | | | | |
|---|---|---|---|---|---|
| **AE Number** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | Fatal (PPD) | NOT RELATED/OTHER: Unknown. Subject was found deceased on the PPD . | 2 | 49 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| Withdrawn | FOLLOW-UP | PPD | DEATH |

| Narrative Comment |
|---|
| Participant PPD, a 60-year-old PPD with no reported medical history, with a BMI of PPD kg/m$^2$ at baseline, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 104).<br><br>Concomitant medication included PPD (since PPD as vitamin supplement.<br><br>The participant died on PPD, 48 days after receiving BNT162b2.<br><br>On PPD (Day 155), the investigator was notified by a Pfizer monitor that the participant died on PPD (Day 152). It was reported that the participant was found dead on the PPD on PPD (Day 152) by PPD The cause of death was unknown, and it was unknown if an autopsy was performed.<br><br>In the opinion of the investigator, there was no reasonable possibility that the death was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 40 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** | **Toxicity Grade** |
| 1 | GASTR | Gastrointestinal haemorrhage | PPD | PPD (137) | | PPD (142) | | 6 | 3 |
| 2 | HEPAT | Hepatomegaly | | PPD (137) | | PPD (157) | | 21 | 1 |
| 3 | CARD | Myocardial infarction | | PPD (147) | | PPD (157) | | 11 | 4 |
| 4 | NERV | Seizure | | PPD (137) | | PPD (142) | | 6 | 1 |
| 5 | VASC | Shock haemorrhagic | | PPD (137) | | PPD (142) | | 6 | 3 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: secondary to PPD induced gastritis | 1 | 137 | N |
| 2 | N | N | Resolved (PPD) | NOT RELATED/OTHER: PPD | 1 | 137 | N |
| 3 | N | Y | Fatal (PPD) | NOT RELATED/OTHER: Recent Hemorrhagic shock | 1 | 147 | Y |
| 4 | N | Y | Resolved (PPD) | NOT RELATED/OTHER: Unknown | 1 | 137 | Y |
| 5 | N | Y | Resolved (PPD) | NOT RELATED/OTHER: GI Bleed | 1 | 137 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| Withdrawn | FOLLOW-UP | PPD | DEATH |

| Narrative Comment |
|---|
| Participant PPD, a 40-year-old PPD with a pertinent medical history of an PPD (from PPD to unknown date), and PPD (since PPD), with a BMI of PPD kg/m$^2$ at baseline, received BNT162b2 on PPD (Day 1).<br><br>Concomitant medication included PPD (PPD; unknown date) for PPD.<br><br>The participant experienced a seizure on PPD, 136 days after receiving BNT162b2, and a myocardial infarction on PPD, 146 days after receiving BNT162b2.<br><br>On PPD (Day 137), the participant woke up feeling sick and had multiple falls (at least 4 times), and vomited blood. PPD also had a syncopal episode. The participant's PPD called the emergency medical services. Upon arrival at the emergency department, the participant was unresponsive with a blood pressure of 60/35 and a respiratory rate of 6. The participant was admitted to the intensive care unit and started on PPD. An esophagogastroduodenoscopy showed moderately severe esophagitis, gastritis, and duodenitis. The hospital record indicated that the participant had a seizure; however, the participant denied a history of seizure and an electroencephalography performed during the hospitalization was normal. The participant also had an elevated liver function test along with hepatomegaly. The participant was treated with PPD. On PPD (Day 142), the hemorrhagic shock secondary to GI bleeding and seizure were considered resolved, and the participant was discharged from the hospital.<br><br>The participant was called to be reminded of the next scheduled visit. However, the site was informed that the participant had passed away on PPD (Day 157) because of a myocardial infarction. It was reported that the participant was hospitalized on PPD (Day 147) because of a myocardial infarction and was on life support for 10 days. On PPD (Day 157), the life support was withdrawn, and the participant died. It was unknown if an autopsy was performed.<br><br>In the opinion of the investigator, there was no reasonable possibility that the seizure and myocardial infarction were related to BNT162b2 or clinical trial procedures, but the myocardial infarction was related to the recent hemorrhagic shock. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

**Reason(s) for Narrative: Death**
**Participant:** PPD **; Country:** PPD
**Vaccine Group (as Administered): BNT162b2 (30 µg)**
**Date of First Dose:** PPD **; Date of Last Dose:** PPD

==========

| Medical History | | | |
|---|---|---|---|
| **Investigator Text** | **MedDRA Preferred Term** | **Start Date** | **Disease Status** |
| PPD | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** |
| 1 | GENRL | Death | PPD | PPD (168) | | PPD (168) | | 1 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 4 | W | Y | Fatal (PPD) | NOT RELATED/OTHER: IDIOPATHIC | 1 | 168 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| Withdrawn | FOLLOW-UP | PPD | DEATH |

| **Narrative Comment** |
|---|
| Participant PPD, a 60-year-old PPD with a pertinent medical history of PPD PPD (since PPD), PPD and PPD (since PPD), PPD (since PPD), PPD PPD (since PPD), and PPD (since PPD), with a BMI of PPD kg/m$^2$ at baseline, received BNT162b2 on PPD (Day 1).<br><br>Concomitant medications included PPD (since PPD for PPD, PPD (since PPD), PPD PPD (since PPD for PPD, PPD (since PPD) for PPD, PPD (since PPD) for PPD, PPD (since PPD for PPD PPD (since PPD) for PPD PPD, PPD (since PPD) for PPD, PPD (since PPD for PPD PPD (since PPD) for PPD PPD (since PPD) as prophylaxis, PPD (since PPD for PPD PPD, and PPD (since PPD for PPD.<br><br>The participant died (sudden cardiac death) on PPD, 167 days after receiving BNT162b2.<br><br>On PPD, after multiple unsuccessful attempts to contact the participant regarding e-diary compliance, the site contacted the participant's emergency contact. During this contact, the participant's relative informed the site that the participant had passed away at home on PPD (Day 168), and the death certificate indicated the cause of death as sudden cardiac death. No autopsy was performed. It was reported that the participant was on PPD for PPD because of regular use of PPD which PPD was taking for PPD.<br><br>In the opinion of the investigator, there was no reasonable possibility that the death was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 30 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (83) | PPD |

Reason(s) for Narrative: Death
Participant: PPD; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD; Date of Last Dose: PPD

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) | Toxicity Grade |
| 1 | INJ&P | Multiple injuries | PPD | PPD (97) | PPD | PPD (97) | PPD | 1 | 4 |
| 2 | INJ&P | PPD | | PPD (97) | PPD | PPD (97) | PPD | 1 | 4 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | N | Y | Fatal (PPD) | NOT RELATED/OTHER: PPD resulting in death | 2 | 15 | Y |
| 2 | N | Y | Resolved (PPD) | NOT RELATED/OTHER: PPD | 2 | 15 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| Withdrawn | FOLLOW-UP | PPD | DEATH |

| Narrative Comment |
|---|
| Participant PPD, a 30 -year-old PPD with a pertinent medical history of PPD (since PPD, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 83).<br><br>Concomitant medication included PPD (since PPD) for PPD<br><br>The participant experienced multiple injuries from PPD on PPD, 14 days after receiving BNT162b2.<br><br>On PPD (Day 97), the participant died from the PPD. No autopsy was performed.<br><br>In the opinion of the investigator, there was no reasonable possibility that the multiple injuries from PPD were related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | ≥75 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (97) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | NEOPL | Adrenocortical carcinoma | PPD | PPD (139) | | PPD (189) | PPD | 51 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 4 | TCVTEN/W | Y | Fatal (PPD) | NOT RELATED/OTHER: abnormal cell growth | 2 | 43 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| Withdrawn | FOLLOW-UP | PPD | DEATH |

| Narrative Comment |
|---|
| Participant PPD, an ≥75-year-old PPD with a pertinent medical history of PPD (since PPD), and PPD (since PPD, with a BMI of PPD kg/m$^2$ at baseline, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 97). The participant had a family history of PPD.<br><br>The participant was diagnosed with high grade adrenocortical carcinoma on PPD, 42 days after receiving BNT162b2.<br><br>On PPD (Day 139), the participant presented to the emergency department with a complaint of lower back pain that initially began 3 months before as a dull aching pain. The pain worsened with "significant muscle spasms" for the past week and the pain score was reported to be 10/10. On PPD (Day 139) and PPD (Day 140), a computed tomography (CT) scan of the abdomen and pelvis showed a |

recent-appearing possible subacute mild to moderate upper and lower endplate compression fracture of the L4 vertebral body, which appeared to be associated with an underlying marrow replacing lesion; new lung nodules at the lung bases; a suspicious adrenal mass on the left; a questionable small mass at the anterior dome of the liver, and the findings were concerning for metastatic carcinoma. The participant was informed that PPD had a metastatic disease and was discharged from the emergency department on PPD (Day 139). On PPD (Day 140), the participant presented to a second emergency room and was treated for L4 vertebral fracture, liver mass, adrenal mass, pulmonary nodules, and PPD On the same day (Day 140), the participant was hospitalized, and a bone (L4) biopsy showed metastatic high-grade adrenocortical carcinoma and flow cytometry studies showed insufficient viable B cells; the sections demonstrated needle cores which were completely effaced by metastatic carcinoma; and the histologic results were suggestive of urothelial origin. On PPD (Day 140), a chest x-ray showed under-inflated lungs and stable chest radiographic findings with no acute cardiopulmonary pathological findings; an electrocardiogram showed sinus bradycardia, ST and T wave abnormalities, suggestive of a lateral ischemia; urine and blood cultures showed no growth; and a SARS-CoV-2 test result was negative. On the same day (Day 140), brain natriuretic peptide was 147 pg/mL (normal range [NR]: 0-99 pg/mL) and international normalized ratio was 0.88 (NR: 0.90-1.10). On the same day (Day 140), the laboratory results showed blood urea of 22 mg/dL (NR: 7-21 mg/dL), blood albumin of 2.5 g/dL (NR: 3.5-5.0 g/dL), albumin/globulin ratio of 0.6 (NR: 1.0-3.0), lymphocyte percentage of 12.5% (NR: 20%-51%), neutrophil count of 9.33 × $10^3$/$mm^3$ (NR: 1.80-8.30 × $10^3$/$mm^3$), neutrophil percentage of 80.1% (NR: 40%-75%), and a white blood cell (WBC) count of 11.64 × $10^3$/$mm^3$ (NR: 4.50-11.00 × $10^3$/$mm^3$). On PPD (Day 141), a CT of the thorax with contrast showed scattered subcentimeter pulmonary nodules (metastatic disease could not be excluded), an irregular mass measuring 6.2 cm within the left adrenal fossa concerning for malignancy and trace pleural effusions, reactive versus malignancy. Positron emission tomography was recommended for further evaluation. On the same day (Day 141), the participant's laboratory results showed blood glucose of 187 mg/dL (NR: 65-110 mg/dL), lymphocyte count of 1.05 × $10^3$/$mm^3$ (NR: 1.20 - 5.60 × $10^3$/$mm^3$), and a WBC count of 13.67 × $10^3$/$mm^3$. On PPD (Day 142), a magnetic resonance imaging of the lumbar spine with and without contrast showed a marrow replacing lesion of the L4 vertebral body; mild to moderate pathologic endplate compression fracture of the L4 vertebral body appearing greatest at the central upper and lower L4 endplates; moderate ventral epidural tumor extending posteriorly from the L4, marrow replacing lesion producing moderate compression of the adjacent ventral thecal sac greatest toward the right; and mild soft tissue tumor extending to the paraspinous soft tissues adjacent to the L4 vertebral body greatest on the left. From PPD (Day 142) through PPD (Day 151), the laboratory test results showed elevated blood urea as high as 41 mg/dL, blood albumin as low as 2.0 g/dL, blood glucose as high as 323 mg/dL, lymphocyte count as low as 0.43 × $10^3$/$mm^3$, neutrophil count as high as 21.31 × $10^3$/$mm^3$, and a WBC count as high as 23.40 × $10^3$/$mm^3$. On PPD (Day 144), a palliative radiotherapy was planned for the participant. Six of 10 planned fractions were completed over the course of a week; however, treatment was interrupted because of bowel impaction, and the participant only completed 1 more fraction after this before electing for hospice care. On PPD (Day 146), the pathology results showed compression fracture of the L4 vertebra as well as masses in the adrenal gland (5.8 cm),

lungs, and liver; the slides showed sheets of epithelioid cells within a myxoid background; the tumor cells had granular amphophilic cytoplasm and variably sized oval nuclei with "salt and pepper" chromatin; mitotic rate was high, with 44 mitoses in 9 high power fields, and necrosis was identified; tumor cells were positive for GATA-3, cytokeratin cocktail, IGF2, SF-1, synaptophysin, and inhibin. On PPD (Day 151), an abdominal x-ray showed abundant stool, particularly within the rectum, with a non-obstructed bowel gas pattern. On PPD (Day 154), the participant was discharged to inpatient hospice for pain management and comfort. Discharge medications included PPD PPD for pain, and PPD . The liver mass, PPD adrenal mass, and pulmonary nodules were a result of primary carcinoma and metastases as well as the L4 vertebral fracture. On PPD (Day 189), the participant died because of disease progression of adrenocortical carcinoma. No autopsy was performed.

In the opinion of the investigator, there was no reasonable possibility that the adrenocortical carcinoma was related to BNT162b2. Pfizer concurred with the investigator's causality assessment.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 70 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |

Reason(s) for Narrative: Death
Participant: PPD; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD; Date of Last Dose: PPD

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (78) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | GENRL | Sudden cardiac death | PPD | PPD (151) | | PPD (151) | | 1 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 4 | W | Y | Fatal (PPD) | NOT RELATED/OTHER: LIFESTYLE | 2 | 74 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| Withdrawn | FOLLOW-UP | PPD | DEATH |

| Narrative Comment |
|---|
| Participant PPD, a 70-year-old PPD with a pertinent medical history of PPD (since PPD), received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 78).<br><br>Concomitant medications included PPD (since PPD, PPD (since PPD), and PPD (since PPD) for PPD.<br><br>The participant died (sudden cardiac death) on PPD, 73 days after receiving BNT162b2.<br><br>The participant's PPD informed the site that the participant died on PPD (Day 151). PPD reported that the participant was found unresponsive in bed and was taken to the hospital. Per the emergency medical service report, the participant was in asystole from initial contact, and received 5 rounds of cardiopulmonary resuscitation and remained in asystole throughout. Prior to arrival at the hospital, the participant received PPD. On physical examination, the participant was found to have an unreactive pulse, no spontaneous respirations, and lungs with diffuse crackles. The participant, with no pulse or heart sounds, no cardiac activity, and cyanotic skin, was declared dead. The primary impression of the physician was cardiac arrest. The cause of death was reported as sudden cardiac death. No autopsy was performed.<br><br>In the opinion of the investigator, there was no reasonable possibility that the sudden cardiac death was related to BNT162b2, concomitant medications, or clinical trial procedures but was related to PPD lifestyle. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| **Date of Birth** | **Age at Enrollment (Years)** | **Race** | **Ethnicity** | **Sex** |
| PPD | 30 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| **Height** | **Weight** | **BMI** | **Date Collected (Study Day)** |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| **Investigator Text** | **MedDRA Preferred Term** | **Start Date** | **Disease Status** |
| PPD | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | Placebo | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** |
| 1 | INFEC | PPD | PPD | PPD (98) | | ONGOING | | |
| 2 | PSYCH | | | PPD (41) | | ONGOING | | |
| 3 | INFEC | Pneumocystis jirovecii pneumonia | | PPD (86) | | PPD (118) | | 33 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 4 | TC | Y | Yes | NOT RELATED/OTHER:PPD | 1 | 98 | N |
| 2 | 3 | TC | N | Yes | NOT RELATED/OTHER: Unknown | 1 | 41 | N |
| 3 | 4 | TC | Y | Fatal (PPD) | NOT RELATED/OTHER: Unknown | 1 | 86 | Y |

| Prohibited Concomitant Medications | | | | |
|---|---|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** | **End Date** | **Route** |
| PPD | | | | |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| | TREATMENT UNBLINDED | | |
| | OPEN LABEL TREATMENT | | |
| Withdrawn | FOLLOW-UP | PPD | DEATH |

Reason(s) for Narrative: Death
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

| Narrative Comment |
| --- |
| PPD |

Reason(s) for Narrative: Death
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | ≤24 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** | **Toxicity Grade** |
| 1 | INV | Blood pressure increased | PPD | PPD (9) | PPD | PPD (9) | PPD | 1 | 2 |
| 2 | GENRL | Chest pain | | PPD (2) | PPD | PPD (169) | PPD | 168 | 1 |
| 3 | GENRL | Chills | | PPD (2) | PPD | PPD (3) | PPD | 2 | 1 |
| 4 | SKIN | Erythema | | PPD (11) | PPD | PPD (13) | PPD | 3 | 1 |
| 5 | GENRL | Feeling hot | | PPD (11) | PPD | PPD (13) | PPD | 3 | 1 |
| 6 | NERV | Headache | | PPD (2) | PPD | PPD (4) | PPD | 3 | 1 |
| 7 | NERV | Headache | | PPD (12) | PPD | PPD (43) | PPD | 32 | 1 |
| 8 | INV | Respiratory rate increased | | PPD (8) | PPD | PPD (9) | PPD | 2 | 2 |
| 9 | CARD | Tachycardia | | PPD (8) | PPD | PPD (9) | PPD | 2 | 2 |
| 10 | CARD | Tachycardia | | PPD (9) | PPD | PPD (10) | PPD | 2 | 1 |
| 11 | SKIN | Urticaria | | PPD (9) | PPD | PPD (9) | PPD | 1 | 1 |
| 12 | SKIN | Urticaria | | PPD (10) | PPD | PPD (13) | PPD | 4 | 1 |

| Adverse Events | | | | | | |
|---|---|---|---|---|---|---|
| **AE Number** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | N | N | Resolved (PPD) | NOT RELATED/OTHER: PPD | 1 | 9 | N |
| 2 | N | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |

Reason(s) for Narrative: Related Serious Adverse Event
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 3 | N | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 4 | N | N | Resolved (PPD) | NOT RELATED/OTHER: unknown | 1 | 11 | N |
| 5 | TCN | N | Resolved (PPD) | NOT RELATED/OTHER: unknown | 1 | 11 | N |
| 6 | TC | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 7 | N | N | Resolved (PPD) | NOT RELATED/OTHER: PPD | 1 | 12 | N |
| 8 | N | N | Resolved (PPD) | NOT RELATED/OTHER: tachycardia/PPD | 1 | 8 | N |
| 9 | TC/TCN | Y | Resolved (PPD) | Study Treatment | 1 | 8 | Y |
| 10 | TC | N | Resolved (PPD) | Study Treatment | 1 | 9 | N |
| 11 | N | N | Resolved (PPD) | NOT RELATED/OTHER: unknown | 1 | 9 | N |
| 12 | TC | N | Resolved (PPD) | NOT RELATED/OTHER: unknown | 1 | 10 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| | TREATMENT UNBLINDED | | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

**Narrative Comment**

Participant PPD, an ≤24-year-old PPD with a pertinent medical history of PPD PPD (since PPD), and PPD (since PPD, received BNT162b2 on PPD (Day 1).

The participant's family medical history included PPD.

Concomitant medications included PPD (unknown; PPD since PPD, and PPD for PPD, and PPD (on PPD) for potential allergic reaction to PPD PPD.

The participant was diagnosed with tachycardia (persistent tachycardia) on PPD, 7 days after receiving BNT162b2.

On PPD, the participant's pediatrician evaluated PPD for PPD PPD were also reported. Cardiology consultation in PPD diagnosed PPD PPD Electrocardiogram (ECG) and 2D echocardiogram were normal. The cardiologist believed the orthostatic findings and associated symptoms reflected dehydration and vasovagal presyncope, with a structurally normal heart. On PPD (Day 1), the participant underwent a gum graft procedure. On PPD (Day 2), the participant experienced intermittent chest pain (nonserious event).

The participant described tachycardia to the cardiologist on PPD (Day 4) at follow-up appointment scheduled prior to onset of the event, described as PPD PPD heart rate at the visit was 129 beats/min (bpm) and the participant had counted 205 bpm. The cardiologist believed the tachycardia and symptoms of orthostasis suggested intravascular fluid depletion; chest pain was atypical for cardiac cause and specifically that it did 'not sound very suggestive of myocarditis.'

The participant received an PPD at PPD on PPD (Day 8); tachycardia and rapid breathing started at PPD. The participant contacted the allergist and reported that the PPD received was PPD instead of the normal PPD and was from a "PPD ." The participant did not have an allergic reaction to PPD previously. The allergist had instructed the participant to take PPD had any symptoms of reactions. Therefore, the participant took the PPD PPD went to the emergency room (ER) at PPD on PPD (Day 9) where PPD pulse was 140 bpm and blood pressure (BP) was 145/93 mmHg. There was no tachycardia resolution over 2 hours and PPD was admitted. An ECG, chest x-ray, and echocardiogram were normal. Laboratory test results showed a white blood cell (WBC) count of 11.98 µL; neutrophils of 89.1% (normal range [NR]: 45% - 80%); platelet count of 235 × $10^3$/µL (NR: 140 – 440 × $10^3$/µL); blood creatinine of 0.71 mg/dL (NR: 0.73 – 1.18 mg/dL); blood glucose of 131 mg/dL (NR: 74 – 99 mg/dL); troponin of <0.010 ng/mL (NR: 0.000 - 0.034 ng/mL); D-dimer of 845 ng/mL FEU (NR: 0 – 500 ng/mL FEU); carbon dioxide of 20 mmol/L (NR: 22 – 29 mmol/L); and total bilirubin of 1.3 mg/dL (NR: 0.1 - 0.8 mg/dL). There was a brief episode of hives. A chest computed tomography (CT) scan performed to rule out pulmonary embolism was normal. The participant was discharged on the same day and was prescribed PPD for tachycardia, but PPD did not take the medication. On PPD (Day 9), the persistent tachycardia (Grade 2) resolved; however, the participant continued to have Grade 1 intermittent tachycardia. The participant returned to the ER on PPD (Day 10) and stated that PPD heart rate and BP were elevated at home prior to the ER visit. The participant had a negative home COVID-19 antigen test (PPD ; on PPD [Day 10]). The participant said the tachycardia episodes differed now as they occurred at rest, and PPD experienced PPD heart beating out of PPD chest'. PPD pulse on arrival to the ER was not known. The participant received PPD Per participant, PPD pulse fell to 150 bpm within 1 hour after PPD The participant also received PPD PPD for vomiting and PPD for hives. The participant was discharged from the ER and instructed to return to ER if pulse was >130 bpm or BP was >180/110 mm Hg. Platelet count was 238 × $10^3$/µL. On PPD (Day 10), the intermittent tachycardia resolved. A cardiology evaluation on PPD (Day 11) recorded a resting pulse of 98 bpm which increased to 125 bpm when standing and resolving again with sitting. BP was normal. Treatments initiated included increased salt intake; PPD PPD ; and compression stockings for PPD legs. The cardiologist felt PPD did not cause but did exacerbate tachycardia. BP and heart rate measurements were taken 3 times during the cardiology appointment to assess PPD . BP remained normal. A 2-week event monitor was ordered. The participant stopped PPD on PPD (Day 11) because of emesis and went to the ER on PPD (Day 12) for emesis and heart racing. The participant's oral temperature in the ER was 98.3ºF; maximum oral temperature during the SAE

was 99.7ºF at home. The participant underwent laboratory tests and procedures on the same day (Day 12), which included urine ketones of 60 mg/dL (NR: negative); WBC count of 8.61 µL (NR: 4.5 - 11.0 µL), neutrophils of 73.0%, total bilirubin of 1.9 mg/dL, blood creatinine of 0.62 mg/dL, and platelet count of 273 × $10^3$/µL. The participant received PPD , PPD PPD . Since urine ketones were noted, PPD was added to PPD and PPD condition improved.

The participant did not have a laboratory COVID-19 test conducted during the hospitalization on PPD (Day 9) or during the ER visits on PPD (Day 10) or PPD (Day 12).

The participant presented to PPD primary care physician (PCP) on PPD (Day 15) with an episode of leg pain. The PCP ran a repeat D-dimer which returned at 1245 (unit and NR not reported) and the PCP ordered a leg ultrasound.

As of PPD (Day 22), the participant had no further episodes of tachycardia while resting but continued to have PPD PPD (as reported previously with PPD ). Mild chest pain continued, intermittently. The participant also cancelled the ultrasound of PPD leg as PPD only had a single episode of leg pain which was felt to be muscular, and PPD therefore did not feel this to be necessary. A repeat D-dimer on PPD (Day 45) was 1014 and the PCP therefore re-ordered the ultrasound of PPD legs.

As of PPD (Day 51), the participant had completed the 2-week event monitor reporting 1 episode of tachycardia while wearing the monitor. The participant had 2 additional episodes since PPD that were not during the monitoring period. These were associated with vomiting and the participant had been referred to a gastroenterologist to evaluate PPD gastrointestinal symptoms.

Per participant contact with the site on PPD (Day 58), PPD had a phone consult with cardiologist to review results of 2-week cardiac event monitor. Results were normal, no indication of cardiac involvement per cardiologist. There was 1 episode of increased heart rate to 195 bpm; cardiologist felt it was related to increased activity and did not feel it was cardiac related. The participant requested a repeat echocardiogram, and this will be repeated in 1-2 months. The cardiologist discussed with the participant that PPD felt PPD could be contributing to PPD symptoms. Ultrasound of the lower extremities on PPD (Day 53) was normal and determined no blood clots. The intermittent chest pain was considered resolved on PPD (Day 169). The participant met with the cardiologist who did not feel there were any "red flags" to indicate anything significant was occurring with the participant.

In the opinion of the investigator, there was a reasonable possibility that the persistent tachycardia was related to BNT162b2 and concomitant medications (PPD ), but unrelated to clinical trial procedures. Pfizer did not concur with the investigator's causality assessment. Per Pfizer, there was no reasonable possibility that the persistent tachycardia was related

to BNT162b2 and commented that the participant's unresolved cardiovascular past medical history (PPD provided a more plausible explanation for the event.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** |
| 1 | INV | Hepatic enzyme increased | PPD | PPD (5) | | PPD (41) | |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Duration (Days)** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 37 | 2 | N | Y | Resolved (PPD) | Study Treatment | 1 | 5 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD , a 60 -year-old PPD with a pertinent medical history of PPD (PPD , since PPD ; PPD , since PPD ; and PPD , since PPD , PPD (since PPD ), PPD (in PPD ), PPD (since PPD ), PPD (in PPD ), PPD (since PPD ), PPD (since PPD , and PPD (since PPD , received BNT162b2 on PPD (Day 1).<br><br>The participant's family medical history included PPD (participant's PPD . |

Concomitant medications included PPD (since PPD for PPD PPD (since PPD ) for PPD and PPD (from PPD to PPD ) for PPD

The participant had increased hepatic enzymes (transient elevated liver enzymes) on PPD , 4 days after receiving BNT162b2.

On PPD (Day 27), the participant was scheduled for a routine yearly check-up, in preparation for which PPD underwent fasting laboratory tests on PPD (Day 5). On PPD (Day 32), the participant was contacted for the 1-month follow-up, during which PPD reported that the laboratory tests performed on PPD (Day 5) showed elevated liver enzymes including elevated alkaline phosphatase (ALP) of 236 IU/L (normal range [NR]: 48 – 121 IU/L), aspartate aminotransferase (AST) of 244 IU/L (NR: 0 – 40 IU/L), alanine aminotransferase (ALT) of 381 IU/L (NR: 0 - 32 IU/L), total bilirubin of 1.3 mg/dL (NR: 0.0 - 1.2 mg/dL), and direct bilirubin of 0.48 mg/dL (NR: 0.00-0.40 mg/dL); and elevated thyroid levels (values not reported). Per medical records, it was reported that PPD liver enzyme values were normal previously (values not available). The participant felt well and had no symptoms, jaundice, itching, or nausea and PPD did not PPD . PPD complete blood count also showed leukopenia and PPD thyroid test was also elevated (values not reported). The dose of PPD On PPD (Day 8), the participant visited the site because of gastrointestinal symptoms (PPD which started 2 days before Visit 1). The participant was prescribed PPD ; however, PPD did not take it. The participant did not remember having a fever higher than 100ºF; however, the physician notes reported that the participant took PPD (PPD ; from PPD [Day 1] to PPD [Day 4]) for PPD On PPD (Day 41), repeat liver function tests (LFTs) were performed which showed normal AST, ALT, and ALP (values not reported); however, the bilirubin was still elevated (total bilirubin of 1.8 mg/dL and direct bilirubin of 0.41 mg/dL). On the same day (Day 41), the increased hepatic enzymes were considered resolved. The investigator considered the increased hepatic enzymes to be medically significant and a possible drug-induced liver injury. On PPD (Day 54), the participant reported to the site. PPD liver enzyme levels were normal as per repeat LFTs, and PPD thyroid medication dosage was increased.

In the opinion of the investigator, there was a reasonable possibility that the increased hepatic enzymes were related to BNT162b2 and PPD , but unrelated to other concomitant medications or clinical trial procedures. Pfizer did not concur with the investigator's causality assessment. Per Pfizer, there was no reasonable possibility that the increased hepatic enzymes were related to BNT162b2 and commented that the role of PPD in association with PPD should be considered as an alternative explanation.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 50 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** |
| 1 | INV | Hepatic enzyme increased | PPD | PPD (17) | | PPD (76) | |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Duration (Days)** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 60 | 2 | N | Y | Resolved (PPD) | Study Treatment | 1 | 17 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD , a 50 -year-old PPD with a pertinent medical history of PPD (since PPD , PPD (since PPD ), and PPD (PPD ; since PPD ), received BNT162b2 on PPD (Day 1).<br><br>Concomitant medications included PPD (from PPD to an unspecified date) and PPD (from PPD to PPD ) for PPD PPD (since PPD ) as prophylaxis, and PPD (since PPD for PPD The dose of PPD was PPD in PPD (stopped on PPD ).<br><br>The participant had increased hepatic enzymes on PPD , 16 days after receiving BNT162b2. |

On an unspecified date in PPD, approximately 2 months before study entry, the participant's laboratory results showed alanine aminotransferase (ALT) of 23, aspartate aminotransferase (AST) of 23, alkaline phosphatase (ALP) of 81, and bilirubin of 0.7 (units and normal ranges [NRs] not reported).

On PPD (Day 17), the participant started experiencing gagging and choking, stomach distention, left upper quadrant (LUQ) bloating and tenderness, fatigue, and nausea with no loss of smell or taste. During the first week of PPD, the participant experienced increased emesis, dysphagia, and gagging, and started to eat only PPD

The participant's symptoms worsened around PPD (Day 45), and PPD consulted PPD primary care physician (PCP) on PPD (Day 49). The laboratory tests performed on the next day (PPD [Day 50]) showed an elevated ALT of 72 IU/L (NR: 0 - 32 IU/L), elevated AST of 56 IU/L (NR: 0 – 40 IU/L), elevated ALP of 160 IU/L (NR: 44 – 121 IU/L), and total bilirubin of 0.5 mg/dL (NR not reported). All other labs were normal 49 days after receiving BNT162b2. The investigator considered the increased hepatic enzymes as medically significant. Per PCP, the increased hepatic enzymes were deemed to be due to PPD As a result, the participant was instructed to stop PPD. The participant also described that PPD was on PPD PPD. Concomitant medications PPD were temporarily discontinued in response to the increased hepatic enzymes.

On PPD (Day 62), the participant's laboratory results showed an elevated ALT of 163 IU/L (NR: 10 - 49 IU/L), AST of 108 IU/L (NR: <34 IU/L), and ALP of 133 IU/L (NR: 46 – 116 IU/L). The prothrombin time, partial thromboplastin time, bilirubin, and creatine phosphokinase values were within normal limits; the clinical chemistry results were normal except for elevated chloride (110) and low albumin levels (3.3) (units and NRs not reported).

On PPD (Day 68), the participant reported that PPD was feeling better after 1 week of discontinuation of PPD PPD. The gagging had stopped, and the LUQ tenderness had also abated. PPD physical examination was normal with no jaundice or palpable hepatomegaly. The participant had slight mid central upper quadrant palpable tenderness in the region of the esophageal gastric junction. On PPD (Day 76), the ALT, AST, and ALP values had returned to normal, and the increased hepatic enzymes were considered resolved.

In the opinion of the investigator, there was a reasonable possibility that the increased hepatic enzymes were related to BNT162b2 and concomitant medications PPD, but unrelated to the clinical trial procedures. Pfizer did not concur with the

investigator's causality assessment. Per Pfizer, there was a reasonable possibility that the increased hepatic enzymes were related to concomitant medications (PPD, but unrelated to BNT162b2.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 70 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |

| Medical History | | | |
|---|---|---|---|
| **Investigator Text** | **MedDRA Preferred Term** | **Start Date** | **Disease Status** |
| PPD | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (73) | PPD |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** |
| 1 | CARD | Acute myocardial infarction | PPD | PPD (9) | | PPD (12) | |
| 2 | GENRL | Injection site pain | | PPD (1) | PPD | PPD (2) | |
| 3 | GENRL | Pain | | PPD (74) | | PPD (74) | |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Duration (Days)** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 4 | 4 | TC/TCN | Y | Resolved (PPD) | Study Treatment | 1 | 9 | Y |

Reason(s) for Narrative: Related Serious Adverse Event; Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | Duration (Days) | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 2 | 2 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 3 | 1 | 1 | TC | N | Resolved (PPD) | Study Treatment | 2 | 2 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 70-year-old PPD with a pertinent medical history of PPD PPD PPD [from PPD to PPD]), PPD (since PPD), PPD (from PPD to PPD, PPD and PPD (since PPD), PPD (since PPD), PPD (from PPD to PPD), PPD (since PPD), PPD (since PPD), PPD (since PPD), PPD (since PPD), and PPD (unknown date), and a BMI of PPD kg/m$^2$ at baseline. The participant's family history included PPD PPD (participant's PPD. The participant received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 73).<br><br>Concomitant medications included PPD (since PPD) for PPD, PPD (from PPD to PPD) for PPD, PPD (both since PPD), and PPD PPD (since PPD) for PPD.<br><br>The participant was diagnosed with a non-ST elevated acute myocardial infarction on PPD, 8 days after receiving placebo.<br><br>On PPD (Day 9), the participant started experiencing chest pain; the pain subsided, but it recurred on PPD (Day 11) and the participant went to the emergency room. On admission, vital signs showed heart rate of 59 beats/min, blood pressure of 138/97 mm Hg, respiratory rate of 19 breaths/min, and oxygen saturation was 99% on room air. The participant had pain (1/10) and mild shortness of breath, and PPD was feeling PPD. On PPD (Day 11), the participant's laboratory results showed an elevated brain natriuretic peptide of 149 pg/mL (normal range [NR]: <100 pg/mL), troponin I of 0.74 ng/mL (NR: 0.00 - 0.04 ng/mL), and fibrin D-dimer of 1.00 µgFEU/mL (NR: <0.49 µgFEU/mL); a chest x-ray was normal with no pleural effusion; a computed tomography pulmonary angiogram showed no pulmonary embolism; and a SARS-CoV-2 test result was negative. The participant was not on any primary cardiac prophylaxis prior to the |

event. On an unspecified date, an echocardiogram showed mildly reduced systolic function with an ejection fraction of 40%-45%. Global hypokinesis with marked apical anteroseptal and apical anterior hypokinesis and no significant valvular abnormalities were noted. A coronary angiogram showed proximal stenosis (80%) of the left anterior descending artery. Mild luminal irregularities (<10%) in the left circumflex artery with no angiographically significant stenosis. Mild luminal irregularities (<10%) in the right coronary artery with past lateral branch with 99% subtotal occlusion. It was reported that the participant had previous PPD (no further information reported). The participant was treated with PPD (on PPD [Day 11]) for anticoagulation, PPD (PPD [Day 11] to PPD [Day 12]) for aspiration pneumonia prevention, PPD (since PPD [Day 11]) for elevated cholesterol, PPD (since PPD [Day 11]) for anticoagulation, PPD (on PPD [Day 12]) for anticoagulation, PPD (from PPD [Day 12] to PPD [Day 13]) for hydration, and PPD for postcoronary intervention (since PPD [Day 12]). On PPD (Day 12), the laboratory results showed troponin I of 3.23 ng/mL and 5.71 ng/mL, hemoglobin A1C of 6.1% (NR: <5.6%), and high-density lipids of 43 mg/dL (NR: >50 mg/dL). Cardiac catheterization was performed, and 2 stents were placed in the right posterior lateral and distal anterior descending arteries, and the myocardial infarction was considered resolved. On PPD (Day 13), the laboratory results showed hematocrit of 32.5% (NR: 34.0% - 46.0%), hemoglobin of 10.3 g/dL (NR: 11.5 - 15.0 g/dL); an electrocardiogram showed sinus rhythm inferior Q waves, T wave abnormality, inferior ischemic ST depression, and subendocardial injury in anterolateral leads. On the same day (Day 13), the participant was discharged home.

In the opinion of the investigator, there was a reasonable possibility that the acute myocardial infarction was related to the placebo, but unrelated to concomitant medications or clinical trial procedures. Pfizer did not concur with the investigator's causality assessment. Per Pfizer, there was no reasonable possibility that the acute myocardial infarction was related to the placebo, concomitant medications, or clinical trial procedures, but was associated with the participant's underlying PPD PPD, and positive family history of PPD from the participant's PPD.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 30 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time |
| 1 | GASTR | Abdominal pain upper | PPD | PPD (1) | PPD | PPD (2) | PPD |
| 2 | MUSC | Arthralgia | | PPD (1) | PPD | PPD (2) | PPD |
| 3 | GENRL | Chest pain | | PPD (6) | | PPD (6) | |
| 4 | GASTR | Diarrhoea | | PPD (1) | PPD | PPD (2) | PPD |
| 5 | MUSC | Myalgia | | PPD (1) | PPD | PPD (2) | PPD |
| 6 | GASTR | Nausea | | PPD (1) | PPD | PPD (2) | PPD |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | Duration (Days) | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 2 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 2 | 2 | 2 | TC | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 3 | 1 | 3 | N | Y | Resolved (PPD) | Study Treatment | 1 | 6 | Y |
| 4 | 2 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 5 | 2 | 2 | TC | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 6 | 2 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| Withdrawn | FOLLOW-UP | PPD | PHYSICIAN DECISION |

| Narrative Comment |
|---|
| Participant PPD, a 30-year-old PPD with a pertinent medical history of PPD PPD (in PPD), PPD (PPD; since PPD, and PPD (unknown dates), received placebo on PPD (Day 1).<br><br>Concomitant medications included PPD (since PPD) for PPD, and PPD (since PPD) for PPD. |

The participant experienced chest pain on PPD, 5 days after receiving placebo.

On PPD (Day 6), the participant was PPD and developed chest pain in the center of PPD chest that was associated with palpitations, shortness of breath, and left arm numbness, which PPD described as a "crampy feeling." PPD heart rate was recorded as 98 beats/min (bpm) PPD reading). The participant reported that PPD felt like PPD might pass out; the pain did not abate, and PPD went to the emergency room (ER) approximately 3 hours after PPD chest pain had started with a concern of myocarditis from the booster vaccination. Notably, troponin T was within normal limits. An electrocardiogram (ECG) showed mild rhythm disturbances, which included sinus rhythm, supraventricular bigeminy with minimal ST depression in inferior leads when compared to the previous ECG (performed on PPD). Per the ER report, a bedside echocardiogram was performed that was normal, but a formal echocardiogram was not performed. No other imaging was performed. Later that same day (Day 6), the chest pain abated without any therapy. The participant stated that the symptoms resolved the same day, but PPD experienced minor residual symptoms, notably palpitations, and PPD was discharged from the emergency department with a plan for follow-up with cardiology. The investigator considered the chest pain to be medically significant.

The participant had a history of PPD, but this typically occurred with PPD, and PPD took PPD. Of note, PPD had taken PPD on PPD (Day 1) for generalized aches. This chest pain was not the same as PPD other episodes of PPD. PPD had a history of PPD but had no recent PPD and PPD had not been problematic for years. In PPD estimation, the chest pain and shortness of breath were not the same as PPD previous PPD PPD did not have any PPD or use any PPD prior to the episode of chest pain. The participant had an PPD in PPD that typically felt like skipped beats and lasted 30 minutes. PPD had no further symptoms of chest pain since the episode on PPD (Day 6). On PPD (Day 32), the participant was seen by a cardiologist. A cardiac stress test showed a baseline heart rate of 66 bpm and increased heart rate of 200 bpm at peak exercise, representing 103% of age-predicted maximum heart rate, resting blood pressure of 108/72 mm Hg and peak blood pressure of 160/60 mm Hg; and the achieved double rate was measured to be 32,000. The participant stated rate of perceived exertion as 19 (Borg Scale 6-20 range) and functional aerobic capacity was 106%. During the procedure, the participant did not develop symptoms of discomfort; however, PPD experienced calf tightness and throat tightness, which resolved with rest. The test was terminated due to fatigue, and PPD was stable at the end of the procedure. An ECG showed normal sinus rhythm and atrial premature complex and the stress ECG showed sinus tachycardia; Duke TMST score was 14 and no significant abnormalities were noted. On physical examination, the participant was alert and cooperative, without any distress; no carotid bruit; lungs clear to auscultation bilaterally; heart sounds were normal S1 and S2 with no rub, gallop, or murmur; extremities showed no cyanosis or edema. On PPD (Day 36), an echocardiogram was normal with an ejection fraction of 64%. The participant was scheduled for further follow-up in 3 months.

The participant was withdrawn from the study on PPD because of the investigator's decision.

In the opinion of the investigator, there was a reasonable possibility that the chest pain was related to the placebo, but unrelated to concomitant medications or clinical trial procedures. Pfizer did not concur with the investigator's causality assessment. Per Pfizer, there was no reasonable possibility that the chest pain was related to the placebo, concomitant medications, or clinical trial procedures.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (85) | PPD |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) | Toxicity Grade |
| 1 | INFEC | Cellulitis | PPD | PPD (125) | | PPD (190) | | 66 | 3 |
| 2 | GENRL | Chills | | PPD (88) | | PPD () | | | 1 |
| 3 | METAB | Diabetes mellitus | | PPD (7) | | ONGOING | | | 2 |
| 4 | NERV | Headache | | PPD (2) | | PPD (11) | | 10 | 1 |
| 5 | NERV | Headache | | PPD (88) | | PPD () | | | 1 |
| 6 | GENRL | Injection site erythema | | PPD (88) | | PPD (95) | | 8 | 1 |
| 7 | GENRL | Injection site erythema | | PPD (103) | | PPD (139) | | 37 | 2 |
| 8 | GENRL | Injection site pruritus | | PPD (103) | | ONGOING | | | 2 |
| 9 | GENRL | Pain | | PPD (88) | | PPD () | | | 1 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | TC | Y | Resolved (PPD) | Study Treatment | 2 | 41 | Y |
| 2 | N | N | Resolved (PPD) | Study Treatment | 2 | 4 | N |
| 3 | TC | N | Yes | NOT RELATED/OTHER: Cause not determined | 1 | 7 | N |
| 4 | N | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 5 | N | N | Resolved (PPD) | Study Treatment | 2 | 4 | N |
| 6 | N | N | Resolved (PPD) | Study Treatment | 2 | 4 | N |
| 7 | TC | N | Resolved (PPD) | Study Treatment | 2 | 19 | N |
| 8 | TC | N | Yes | Study Treatment | 2 | 19 | N |
| 9 | N | N | Resolved (PPD) | Study Treatment | 2 | 4 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 60 -year-old PPD with a pertinent medical history of PPD (since PPD) and PPD (since PPD), with a BMI of PPD kg/m$^2$ at baseline, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 85).<br><br>Concomitant medications included PPD (since PPD) for PPD, and PPD (since PPD) and PPD (since PPD) for PPD.<br><br>The participant was diagnosed with cellulitis on PPD, 40 days after receiving BNT162b2.<br><br>During the 1-month telephone contact 2 visit, the participant reported erythema of the left upper arm a few days after receiving BNT162b2 in the left deltoid on PPD (Day 85). On approximately PPD (Day 88), the participant noted erythema, which was moderate in color and about 2-3 inches in diameter at the injection site extending to the elbow. The participant denied tenderness, pain, pruritus, edema, scaling, necrosis, or streaking. The injection site erythema resolved completely in approximately 1 week by PPD (Day 95).<br><br>On PPD (Day 103), the injection site (left upper arm) erythema recurred along with pruritus and was warm to the touch. The investigator contacted the Pfizer study medical monitor to report the atypical pattern and recurrence of erythema and to inquire whether other study participants had presented with a delayed response similar to this participant, which initially appeared to be an allergic response. Upon review of the clinical database, the Pfizer medical monitor did not identify other similar cases. The investigator believed the event was a delayed hypersensitivity reaction and not an infection. On PPD (Day 114), the participant was instructed to start PPD on the erythematous lesion. The participant continued to have pruritus and was advised to take PPD. The participant took only PPD but did not notice any change. PPD also had mild scaling over the affected area of the left arm. The participant had an unscheduled visit because of PPD ongoing condition and reported to have taken PPD but not at the PPD since it caused drowsiness. The participant continued to apply PPD with only slight improvement. The participant had another unscheduled visit because of PPD condition with scaling, slightly warm to the touch, and slight swelling (11.25 cm vs 12 cm over mid biceps) of the area. Erythema of >10 cm was noted although it was not as well circumscribed as earlier. On examination, no signs of infection were observed, and it still appeared to be an allergic reaction, so the participant was advised to continue with treatment until consultation with an allergist. Later, the allergist also noted that the erythema appeared to be a delayed allergic reaction, and the participant was advised to start PPD but only over a |

small portion of the erythema to determine the improvement compared to an untreated area. A skin biopsy was recommended if no improvement was observed.

On PPD (Day 122), the participant began treatment with PPD over a small area. After using PPD for PPD it was determined that the PPD helped, especially with flaking. The participant felt that PPD rash looked better, and PPD upper arm itching was mostly around a distal portion of PPD upper arm above the elbow. The participant had symptoms that included sharp pains like pins and needles over the proximal aspect of the left upper arm with decreased mobility which was worse in the morning but got better as PPD used PPD arm. In addition, the participant developed systemic symptoms, including significant fatigue upon awakening along with an intense headache and a cold sweat, which resolved the next day.

On PPD (Day 125), the participant had more fatigue and continued to have pruritus. On the next day (Day 126), the participant felt warm and had a fever of slightly above 101°F. PPD also had sweating and noted that the redness over the left arm became darker. The participant was referred to PPD primary care physician (PCP) with a concern of cellulitis. The physician concurred that it appeared to be a cellulitis and the participant was treated with PPD starting PPD (Day 127). The investigator considered the cellulitis to be medically significant. On PPD (Day 132), the participant noted improvement with decreased erythema; however, pruritus was still present along with dull pain with movement of the left arm. On PPD (Day 136), the participant noted that the inflammation and erythema had decreased. However, PPD experienced pain in the left arm when bending and felt PPD strength had decreased. The participant stated that PPD could barely lift 10 lbs. PPD was unable to keep PPD arm stretched all the time. The PPD was completed on PPD (Day 137). The participant noted great improvement in appearance of PPD arm on PPD (Day 138); however, PPD still had pain above the elbow when twisting or bending PPD arm and had difficulty lifting any weight. On PPD (Day 139), the erythema resolved. On PPD (Day 141), the participant had a follow-up visit with PPD PCP and reported that PPD continued to have upper arm pain and weakness, so PPD was referred to an orthopedist. On PPD (Day 143), the laboratory results showed a sedimentation rate of 106 mm/hour (normal range [NR]: 0-30 mm/hour) and a C-reactive protein of 28 mg/L (NR: 0-10 mg/L). On PPD (Day 148), the participant reported improvement in movement and strength in the left arm; however, PPD continued to have pruritus and paresthesia that radiated to the neck. The participant had a consultation with an orthopedist, who recommended a magnetic resonance imaging (MRI) to rule out a minor tear of the left upper muscles. On PPD (Day 148), the MRI was performed, which showed diffuse, nonspecific soft tissue edema of the left arm, and the muscle of the left upper arm and humerus were normal.

On PPD (Day 150), the participant continued to have pruritus and burning of the left arm radiating to the neck. The orthopedist recommended PPD but the participant refused so the investigator advised the participant to take PPD .

As of PPD (Day 154), the participant had no change in PPD symptoms even with PPD and had difficulty sleeping. The participant began treatment with PPD on the same day until PPD (Day 159) with great improvement in PPD symptoms. However, on PPD (Day 165), the participant had redness and itching extending all over PPD body, especially on the "sides, under arms". On PPD (Day 170), the participant had a follow-up visit with PPD PCP because of a rash on PPD trunk, axillae, and beltline. The participant was diagnosed with tinea corporis based on location, appearance, and use of recent PPD , and treatment with PPD was initiated. The participant noted improvement of PPD symptoms (pruritus and burning). On PPD (Day 178), after 8 days of treatment, the participant felt better, and the rash was resolving. On PPD (Day 190), the participant reported mild pruritus, the rash had resolved, and PPD was off the medication for approximately 1 week. On the same day (Day 190), the left arm cellulitis was considered resolved.

In the opinion of the investigator, there was a reasonable possibility that the cellulitis was related to BNT162b2, but unrelated to concomitant medications or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |

| Medical History | | | |
|---|---|---|---|
| **Investigator Text** | **MedDRA Preferred Term** | **Start Date** | **Disease Status** |
| PPD | | | Past |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (105) | PPD |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** |
| 1 | RESP | Chronic obstructive pulmonary disease | PPD | PPD (107) | | PPD (122) | |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Duration (Days)** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 16 | 2 | TC | Y | Resolved (PPD) | Study Treatment | 2 | 3 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD , a 60 -year-old PPD with a pertinent medical history of PPD (since PPD ), PPD PPD (since PPD ), PPD (PPD , since PPD , PPD (since |

PPD , PPD (since PPD , and PPD (PPD ; since PPD , with a BMI of PPD kg/m$^2$ at baseline, received placebo on PPD (Day 1), and BNT162b2 on PPD (Day 105).

Concomitant medications included PPD (since PPD ) for PPD , PPD (since PPD for PPD , PPD (since PPD ) for PPD , PPD (from PPD to PPD ), PPD (since PPD ), and PPD (since PPD ) for PPD , PPD (since PPD ) for PPD and PPD (since unspecified date) for PPD .

The participant was diagnosed with COPD exacerbation on PPD , 2 days after receiving BNT162b2.

On PPD (Day 111), the participant reported COVID-19 symptoms and stated that PPD had been experiencing dark, tarry stools, mild elevated temperature, excessive throat secretions, chills, nasal discharge, diarrhea, and vomiting since PPD (Day 107). That same day (Day 111), the participant visited PPD primary care physician (PCP) with complaint of shortness of breath and the emergency medical services (EMS) were called. The EMS reported that the participant's oxygen saturation was in the 70s while at PPD PCP's office and they could not get the levels to rise. The participant was referred to the emergency room for further management and evaluation. While in the emergency room, PPD oxygen saturation was in the low 80s on room air, requiring 4 L of oxygen via nasal cannula. PPD did not have heart failure or a history of pulmonary edema. The participant was diagnosed with COPD exacerbation with acute bronchitis and hypoxia. On PPD (Day 111), the SARS-CoV-2 test and flu test results were negative. A blood gas analysis showed high levels of partial pressure of carbon dioxide at 64.5 mm Hg, blood bicarbonate at 34.8 mmol/L and base excess at 6.8 mmol/L and low levels of partial pressure of oxygen at 72.7 mm Hg with a low oxygen saturation of 93.6%. The laboratory results showed high levels of carboxyhemoglobin of 3.2%, absolute neutrophil count of 7.6 × 10$^3$/µL, carbon dioxide of 33 mmol/L, and glucose of 112 g/dL; low levels of oxyhemoglobin of 90.4%, chloride of 93 mmol/L, and albumin of 3.3 g/dL (normal range not provided). A chest x-ray showed normal cardiomediastinal silhouette size with clear lungs without any acute findings. While in the emergency room, the participant was treated with PPD . The dark stools were believed to be due to the participant's PPD and a gastrointestinal consult was not considered necessary. The participant was admitted to the hospital on the next day (Day 112). On admission to the hospital, the participant had a body temperature of 35.8ºC, blood pressure of 140/68, heart rate of 90, and an oxygen saturation of 94%.

On PPD (Day 115), a sputum culture was negative. On PPD (Day 116), the participant was diagnosed with pneumonia. On the same day (Day 116), the participant was discharged from the hospital on PPD

PPD , and home oxygen. PPD was advised to take PPD . The participant had an oxygen saturation of 89% on room air at the time of discharge. PPD other discharge medications included PPD PPD . On PPD (Day 122), the COPD exacerbation and pneumonia resolved.

In the opinion of the investigator, there was a reasonable possibility that the COPD exacerbation was related to the BNT162b2, but unrelated to concomitant medications or clinical trial procedures. Pfizer did not concur with the investigator's causality assessment. Per Pfizer, there was no reasonable possibility that the COPD exacerbation was related to BNT162b2 and considered the COPD exacerbation as most likely related to the underlying PPD .

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | Placebo | PPD (1) | PPD |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** |
| 1 | INV | Alpha 1 foetoprotein increased | PPD | PPD (46) | | ONGOING | |
| 2 | GASTR | Ascites | | PPD (53) | | ONGOING | |
| 3 | NEOPL | Hepatic cancer metastatic | | PPD (51) | | ONGOING | |
| 4 | HEPAT | Hepatic cirrhosis | | PPD (55) | | ONGOING | |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Duration (Days)** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | | 2 | N | N | Yes | NOT RELATED/OTHER: hepatocellular CA | 1 | 46 | N |
| 2 | | 2 | TC | N | Yes | NOT RELATED/OTHER: Cirrhosis | 1 | 53 | N |
| 3 | | 4 | TCN/W | Y | Yes | NOT RELATED/OTHER: IDIOPATHIC | 1 | 51 | Y |
| 4 | | 3 | N | N | Yes | NOT RELATED/OTHER: Idiopathic | 1 | 55 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| | TREATMENT UNBLINDED | | |
| | OPEN LABEL TREATMENT | | |
| Withdrawn | FOLLOW-UP | PPD | ADVERSE EVENT |

| Narrative Comment |
|---|
| Participant PPD, a 60-year-old PPD with a pertinent medical history of PPD (since PPD), PPD and PPD (since PPD), and PPD (since PPD), with a BMI of PPD kg/m$^2$ at baseline, received placebo on PPD (Day 1).<br><br>Concomitant medications included PPD (since PPD) for PPD, PPD (since PPD) for PPD, PPD (since PPD) and PPD (since PPD) for PPD, and PPD (since PPD) for PPD.<br><br>The participant was diagnosed with metastatic hepatic cancer on PPD, 50 days after receiving placebo.<br><br>It was reported that the participant had increased alpha-1-fetoprotein and was diagnosed with a right lobe liver mass since PPD (Day 46). On PPD (Day 51), the participant's PPD called to notify the site that the participant was diagnosed with metastatic hepatic cancer, which was considered life-threatening. On PPD (Day 53), the laboratory results showed high levels of alanine aminotransferase of 120 IU/L, aspartate aminotransferase of 156 IU/L, and blood alkaline phosphatase of 189 (unit and normal range were not provided). The activated partial thromboplastin time was prolonged at 75 seconds, prothrombin time prolonged at 67.3 seconds, and international normalized ratio elevated at 7.8 (normal ranges were not provided for any of the lab parameters). The albumin level was low (3.2 g/dL). The participant developed ascites on PPD (Day 53) and was diagnosed with hepatic cirrhosis on PPD (Day 55). On PPD (Day 54), the participant was placed in hospice care. No further information was obtained. PPD was treated with PPD starting on PPD (Day 56) and PPD starting on PPD (Day 56).<br><br>The participant was withdrawn from the study on PPD because of the metastatic hepatic cancer, which was ongoing at the time of withdrawal. The increased alpha-1-fetoprotein, ascites, and hepatic cirrhosis were ongoing at the time of withdrawal.<br><br>In the opinion of the investigator, there was no reasonable possibility that the metastatic hepatic cancer was related to the placebo, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 70 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | Placebo | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** |
| 1 | GASTR | Diarrhoea | PPD | PPD (1) | | PPD (3) | | 3 |
| 2 | INV | Precancerous cells present | | PPD (122) | | ONGOING | | |
| 3 | GENRL | Pyrexia | | PPD (1) | | PPD (3) | | 3 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 2 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 2 | 1 | TC/P | N | Yes | NOT RELATED/OTHER: Skin irritation | 1 | 122 | Y |
| 3 | 3 | TC/TCN | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| Withdrawn | FOLLOW-UP | PPD | PROTOCOL DEVIATION |

| Narrative Comment |
|---|
| Participant PPD, a 70 -year-old PPD with a pertinent medical history of PPD PPD; since PPD ), received placebo on PPD (Day 1).<br><br>The participant was diagnosed with presence of precancerous cells (on nose) on PPD, 121 days after receiving placebo.<br><br>The participant was withdrawn from the study on PPD because of the presence of the precancerous cells and a protocol deviation. The precancerous cells were ongoing at the time of the withdrawal.<br><br>In the opinion of the investigator, there was no reasonable possibility that the presence of the precancerous cells was related to the placebo but was related to a skin irritation. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 50 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

| Medical History | | | |
|---|---|---|---|
| **Investigator Text** | **MedDRA Preferred Term** | **Start Date** | **Disease Status** |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (91) | PPD |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** |
| 1 | MUSC | Arthralgia | PPD | PPD (25) | | ONGOING | |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time |
| 2 | VASC | Deep vein thrombosis | PPD | PPD (138) | | ONGOING | |
| 3 | VASC | Superficial vein thrombosis | | PPD (124) | | ONGOING | |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | Duration (Days) | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | | 1 | N | N | Yes | NOT RELATED/OTHER: PPD injury | 1 | 25 | N |
| 2 | | 2 | TC | Y | Yes | NOT RELATED/OTHER: TRAUMA | 2 | 48 | Y |
| 3 | | 2 | TC | N | Yes | NOT RELATED/OTHER: trauma | 2 | 34 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| **Narrative Comment** |
|---|
| Participant PPD, a 50-year-old PPD with a pertinent medical history of PPD (PPD PPD since PPD), PPD (since PPD), PPD (in PPD), PPD (since PPD), PPD (PPD; since PPD), PPD (PPD; since PPD), PPD (PPD; since PPD), PPD (PPD; since PPD, PPD (since PPD), PPD (PPD; on PPD), and PPD (since PPD), received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 91).<br><br>The participant was diagnosed with a deep vein thrombosis on PPD, 47 days after receiving BNT162b2.<br><br>On PPD (Day 107), the participant reported falling during an PPD which resulted in left knee swelling and pain. On PPD (Day 116), the participant began experiencing pain, redness, and hardness in PPD left leg behind the knee. On PPD (Day 124), a doppler ultrasound showed chronic nonocclusive deep vein thrombosis with acute superficial vein thrombosis (SVT) in the left lower extremity. On PPD (Day 138), the pain in the left lower extremity worsened and a repeat doppler ultrasound showed an extension of previously seen acute SVT along with nonocclusive deep venous thrombosis. The investigator considered the deep vein thrombosis to be medically significant. An unspecified anticoagulant therapy was started on the same day (Day 138). The deep vein thrombosis and superficial vein thrombosis were ongoing at the time of the last available report.<br><br>In the opinion of the investigator, there was no reasonable possibility that the deep vein thrombosis was related to BNT162b2 or clinical trial procedures but was related to the trauma. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 70 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Past |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) | Toxicity Grade |
| 1 | INJ&P | Acetabulum fracture | PPD | PPD (9) | | ONGOING | | | 3 |
| 2 | CARD | Acute myocardial infarction | | PPD (9) | | PPD (9) | | 1 | 4 |
| 3 | INJ&P | Fall | | PPD (9) | | PPD (9) | | 1 | 3 |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) | Toxicity Grade |
| 4 | MUSC | Joint effusion | PPD | PPD (9) | | ONGOING | | | 2 |
| 5 | INJ&P | Pelvic fracture | | PPD (9) | | ONGOING | | | 3 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | TCN | Y | Yes | NOT RELATED/OTHER: Not related to drug or non-drug treatment | 1 | 9 | N |
| 2 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: unknown | 1 | 9 | Y |
| 3 | N | N | Resolved (PPD) | NOT RELATED/OTHER: due to Non-Stemi Type II | 1 | 9 | N |
| 4 | TCN | N | Yes | NOT RELATED/OTHER: Not related to drug or non-drug treatment | 1 | 9 | N |
| 5 | TCN | Y | Yes | NOT RELATED/OTHER: not related to study drug or treatment | 1 | 9 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD , a 70 -year-old PPD with a pertinent medical history of PPD (since PPD ), PPD (since PPD , PPD (in PPD , and PPD (since PPD , received BNT162b2 on PPD (Day 1).<br><br>Relevant concomitant medications included PPD (since PPD for PPD PPD (since PPD for PPD , PPD (since PPD for PPD , PPD (since PPD ) as PPD PPD (since PPD for PPD , PPD (since PPD ), PPD and PPD (since PPD ) for PPD , PPD (since PPD for PPD , and PPD (since PPD ) for PPD PPD . |

The participant was diagnosed with an acute myocardial infarction (non-STEMI Type II) on PPD, 8 days after receiving BNT162b2.

On PPD (Day 29), the study site was informed of the participant's hospitalization. It was reported that the participant presented to the emergency department following a syncopal episode and fall with injury sustained on PPD (Day 9). The chest x-ray was normal; an x-ray of the right hip showed nondisplaced acute fractures of the right acetabulum and right inferior pubic ramus and the x-ray of the right elbow showed nonspecific small joint effusion. On the same day (Day 9), an echocardiogram showed a mildly dilated left atrium and dilated right ventricle with reduced systolic function and an electrocardiogram showed incomplete right bundle branch block, mild ST segment elevation in L1 and aVL and T wave inversion in aVL and V1. The participant's troponin level was significantly elevated (at 3324, 8391, 9200; units and normal range not reported), and PPD underwent left heart catheterization which showed coronary artery disease with 25% occlusion of the proximal left anterior descending (LAD) artery, 50% occlusion in the middle segment of the LAD, 50% occlusion of the first diagonal artery ostium, and 25% occlusion of the middle segment of the circumflex artery. Overall left ventricular systolic and diastolic functions were normal without any evidence of infarction, and an ejection fraction of 60% was noted. The left ventricular end-diastolic pressure was 18 mm Hg, mitral valve ring in place, with no evidence of mitral valve regurgitation or aortic stenosis. On the same day (Day 9), the acute myocardial infarction resolved; however, the participant remained hospitalized because of the pelvic and acetabulum fractures. The investigator considered the acute myocardial infarction as life-threatening. On PPD (Day 15), the participant was discharged to a skilled nursing facility for rehabilitation. The participant was started on PPD from PPD (Day 21). The acetabulum and pelvic fractures and joint effusions were ongoing at the time of the last available report.

In the opinion of the investigator, there was no reasonable possibility that the acute myocardial infarction was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the acute myocardial infarction was due to coronary artery stenosis (25%-50% occlusion) attributed to the underlying contributing factors, including PPD.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |

**Reason(s) for Narrative: Adverse Event of Clinical Interest**
**Participant:** PPD **; Country:** PPD
**Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)**
**Date of First Dose:** PPD **; Date of Last Dose:** PPD
==========

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (141) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** |
| 1 | CARD | Myocardial infarction | PPD | PPD (13) | | PPD (13) | | 1 |
| 2 | CARD | Pericarditis | | PPD (67) | | PPD (112) | | 46 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 4 | TC/TCN | Y | Resolved (PPD) | NOT RELATED/OTHER: PPD Progression | 1 | 13 | Y |
| 2 | 2 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: Post bypass surgery | 1 | 67 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 60 -year-old PPD with a pertinent medical history of PPD PPD (since PPD ), PPD (since PPD ), and PPD (since PPD ), with a BMI of PPD kg/m$^2$ at baseline, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 141).<br><br>Concomitant medications included PPD (both since PPD and PPD (since PPD for PPD PPD (since PPD ) for PPD , PPD (since PPD and PPD (since PPD for PPD , PPD (since PPD ) as a supplement, PPD (since PPD ) for PPD , and PPD (since PPD for PPD . The participant was diagnosed with a myocardial infarction on PPD , 12 days after receiving placebo, and pericarditis on PPD , 66 days after receiving placebo. |

On PPD (Day 13), the participant visited the emergency room with chest pain and was hospitalized for a myocardial infarction. A SARS-CoV-2 test performed prior to admission was negative. Stenting was attempted but was unsuccessful. Subsequently, the participant underwent triple bypass surgery on the same day (Day 13). PPD received PPD PPD (all since PPD [Day 13]). The participant was also treated with PPD PPD from PPD (Day 13) to PPD (Day 16), PPD since PPD (Day 13), and PPD since an unknown date for postsurgical pain. The myocardial infarction resolved on PPD (Day 13) and the participant was discharged from the hospital on PPD (Day 23).

The participant continued to have chest pain after surgery. On PPD (Day 67), the participant had a cardiology consultation. An echocardiogram was performed, which showed pericarditis, which was considered medically significant. The participant was treated with PPD, starting on PPD (Day 67). The pericarditis resolved on PPD (Day 112). The participant had another echocardiogram performed on PPD (Day 117); however, the results were pending at the time of the last available report.

In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction and pericarditis were related to the placebo, concomitant medications, or clinical trial procedures. Per investigator, the myocardial infarction and pericarditis were related to the PPD progression and post bypass surgery, respectively. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the myocardial infarction was attributed to the participant's underlying contributory conditions including PPD .

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | ≥75 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Past |

**Reason(s) for Narrative: Adverse Event of Clinical Interest**
**Participant:** PPD **; Country:** PPD
**Vaccine Group (as Administered): Placebo**
**Date of First Dose:** PPD **; Date of Last Dose:** PPD

==========

| Medical History | | | |
|---|---|---|---|
| **Investigator Text** | **MedDRA Preferred Term** | **Start Date** | **Disease Status** |
| PPD | | | Past |
| | | | Present |
| | | | Past |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | Placebo | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** |
| 1 | INJ&P | Fall | PPD | PPD (71) | | PPD (71) | | 1 |
| 2 | NEOPL | Pancreatic carcinoma | | PPD (17) | | ONGOING | | |
| 3 | INJ&P | Thoracic vertebral fracture | | PPD (71) | PPD | ONGOING | | |
| 4 | NERV | Toxic leukoencephalopathy | | PPD (73) | | ONGOING | | |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 3 | N | N | Resolved (PPD) | NOT RELATED/OTHER: unknown | 1 | 71 | N |
| 2 | 4 | N | Y | Yes | NOT RELATED/OTHER: cancer | 1 | 17 | N |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 3 | 3 | N | Y | Yes | NOT RELATED/OTHER: Fall | 1 | 71 | N |
| 4 | 4 | TC/TCN | Y | Yes | NOT RELATED/OTHER: UNK | 1 | 73 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

**Narrative Comment**

Participant PPD, a ≥75-year-old PPD with a pertinent medical history of PPD (since PPD, PPD (since PPD), PPD (in PPD, PPD (since PPD), PPD (in PPD), PPD PPD (unknown date), received placebo on PPD (Day 1).

Concomitant medications included PPD (since PPD and PPD (since PPD for PPD, PPD, PPD (since PPD for PPD, PPD (since PPD for general health, PPD (since PPD) for an unspecified indication, PPD PPD (since PPD for PPD, and PPD (since PPD for PPD.

The participant was diagnosed with toxic leukoencephalopathy on PPD, 72 days after receiving placebo.

On PPD (Day 15), the participant underwent an esophagogastroduodenoscopy with ultrasound, which showed a suspicious mass on the tail of the pancreas; and a computerized tomography (CT) scan confirmed the mass on PPD (Day 17). Fine needle biopsies were done on PPD (Day 17) and PPD (Day 18), and the pathology reports revealed pancreatic tail mass-positive for malignant adenocarcinoma of the pancreas. The participant consulted a surgical and radiation oncologist. Chemotherapy was planned for one month before re-evaluation by the surgical oncologist. A 'mediport' was planned to be placed in anticipation of chemotherapy regimen.

On PPD (Day 71), the participant had a fall resulting in T6 and T7 fracture and was admitted to the emergency room for the treatment of thoracic vertebral fractures.

On an unspecified date, the site contacted the participant's PPD, who informed the study coordinator that the participant was currently incoherent, and PPD was unsure how long the participant had been incoherent. The participant was admitted to the hospital on PPD (Day 73) because of a chemotherapy port infection. The participant's PPD stated that the participant had been seen at other hospitals, was now at a care center, and was diagnosed with toxic leukoencephalopathy, which caused significant disability.

The pancreatic carcinoma, thoracic vertebral fracture, and toxic leukoencephalopathy were ongoing at the time of the last available report.

In the opinion of the investigator, there was no reasonable possibility that the toxic leukoencephalopathy was related to the placebo or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 70 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) | Toxicity Grade |
| 1 | MUSC | Arthritis | PPD | PPD (193) | | ONGOING | | | 1 |
| 2 | EYE | Macular degeneration | | PPD (177) | | ONGOING | | | 1 |
| 3 | MUSC | Metatarsalgia | | PPD (193) | | ONGOING | | | 1 |
| 4 | INFEC | Tooth infection | | PPD (146) | | PPD (156) | PPD | 11 | 1 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | N | N | Yes | NOT RELATED/OTHER: MUSCULOSKELETAL | 1 | 193 | Y |
| 2 | TC | N | Yes | Study Treatment | 1 | 177 | N |
| 3 | TC | N | Yes | NOT RELATED/OTHER: musculoskeletal | 1 | 193 | N |
| 4 | TC | N | Resolved (PPD) | NOT RELATED/OTHER: BACTERIAL | 1 | 146 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| | TREATMENT UNBLINDED | | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD , a 70 -year-old PPD with a pertinent medical history of PPD (since PPD ) and PPD (since PPD , with a BMI of PPD kg/m$^2$ received BNT162b2 on PPD (Day 1).<br><br>The participant experienced arthritis (left great toe) on PPD , 192 days after receiving BNT162b2.<br><br>On the same day (Day 193), the participant experienced left foot metatarsalgia. The arthritis and metatarsalgia were ongoing at the time of the last available report.<br><br>In the opinion of the investigator, there was no reasonable possibility that the arthritis was related to BNT162b2 but was related to the musculoskeletal cause. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 70 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | CARD | Acute myocardial infarction | PPD | PPD (72) | PPD | PPD (77) | | 6 |
| 2 | RESP | Acute respiratory failure | | PPD (72) | PPD | PPD (77) | | 6 |
| 3 | CARD | Atrial fibrillation | | PPD (72) | PPD | PPD (77) | | 6 |
| 4 | CARD | Cardiac failure | | PPD (72) | PPD | PPD (77) | | 6 |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 3 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: Unknown | 1 | 72 | Y |
| 2 | 3 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: Unknown | 1 | 72 | N |
| 3 | 3 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: Unknown | 1 | 72 | N |
| 4 | 3 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: Unknown | 1 | 72 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |

PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_ubBIA/C4591031_6M_Booster_Safety_Narrative/profile. (Cutoff Date: 08FEB2022, Snapshot Date: 03MAR2022) Date of Generation: 24MAR2022 (15:37)

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

**Narrative Comment**

Participant PPD, a 70-year-old PPD with a pertinent medical history of PPD and PPD PPD (since PPD, PPD (since PPD, PPD (since PPD), a history of PPD PPD, with a BMI of PPD kg/m$^2$ at baseline, received BNT162b2 on PPD (Day 1).

Concomitant medications included PPD (since PPD for PPD, PPD (since PPD) as cardiovascular protection, PPD (from PPD to PPD) for PPD, PPD (since PPD) as PPD supplement, and PPD (since PPD) as PPD supplement.

The participant was diagnosed with an acute myocardial infarction on PPD, 71 days after receiving BNT162b2.

On PPD (Day 72) at PPD AM, the participant arrived at the emergency department with the complaints of increased shortness of breath and chest pain that started about PPD AM the previous night. The participant had constant substernal chest pain characterized as pressure that aggravated with activity and improved with rest, which was associated with palpitations, shortness of breath, fatigue, nausea, and vomiting. The participant also reported that PPD had a cough for the past couple of days, which PPD attributed to PPD. The initial electrocardiogram showed atrial fibrillation with rapid ventricular rate of 152 (new onset) along with T wave inversion in the inferior lateral region and a non-ST elevation myocardial infarction. Subsequently, the participant was treated with PPD with improvement in heart rate. However, PPD had a precipitous drop in blood pressure that improved with PPD. PPD heart rate began to increase again to the 120's, so PPD was given PPD and shortly afterward spontaneously converted into normal sinus rhythm but with doing so, PPD transiently became severely bradycardic and syncopized. PPD heart rate improved without intervention and the participant

returned to normal mental status. The participant reported that PPD chest discomfort improved after PPD heart rate improved, and it resolved when PPD converted to normal sinus rhythm. The initial troponin level was elevated to 1.71 (unit and normal range [NR] not reported), which was suspected to be demand ischemia. The participant was stabilized in the emergency department. A chest x-ray showed streaky right basilar lung opacities, atelectasis versus bronchiolitis, suggestive of fluid overload. A transthoracic echocardiography showed regional wall abnormalities. A SARS-CoV-2 test result was negative. The relevant laboratory results included blood gas analysis: pH of 7.4, $pCO_2$ of 40 mm Hg, $pO_2$ of 64 mm Hg, bicarbonate of 24.8 mmol/L, base excess of 0 mmol/L, and total carbon dioxide of 26 mmol/L; mean cell volume of 96 fl, neutrophils of 84.3%, lymphocytes of 9.3%; and high glucose fingerstick of 315 mg/dL with glucose level of 144 mg/dL, cholesterol of 245 mg/dL, triglycerides of 157 mg/dL, troponin of 1.87 ng/mL, direct bilirubin of 0.4 mg/dL (NR not provided for these parameters), aspartate aminotransferase (AST) of 1490 IU/L (NR: 14-36 IU/L) and alanine aminotransferase (ALT) of 1309 IU/L (NR: 0-34 IU/L).

The participant was admitted for further evaluation and treatment. Upon admission, the troponin level was 1.1. A cardiac catheterization performed on the same day (Day 72) revealed single vessel coronary disease with 70% mid left circumflex stenosis, which was a nondominant vessel, right dominant coronary circulation, elevated left heart filling pressure, left ventricular end diastolic pressure of 37 mmHg. Mild cardiomyopathy with a left ventricular ejection fraction of 45%, left anterior descending mid-vessel lesion with 50% stenosis, and left circumflex mid-vessel lesion with 70% stenosis. On PPD (Day 73), the chest x-ray showed worsening perihilar and basilar opacities bilaterally, suggestive of worsening fluid overload with a possible superimposed infection. No pneumothorax or large pleural effusion was observed. The laboratory results showed AST of 436 IU/L, 203 IU/L, and 136 IU/L on PPD (Day 74), PPD (Day 75), and PPD (Day 76), respectively, and ALT of 819 IU/L, 680 IU/L, and 604 IU/L on PPD (Day 74), PPD (Day 75), and PPD (Day 76), respectively. On PPD (Day 77), the new onset atrial fibrillation, decompensated heart failure, acute myocardial infarction, and acute respiratory failure with hypoxia resolved, and the participant was discharged from the hospital. Discharge medications included PPD .

In the opinion of the investigator, there was no reasonable possibility that the acute myocardial infarction was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (143) | PPD |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) | Toxicity Grade |
| 1 | INFEC | COVID-19 pneumonia | PPD | PPD (34) | | PPD (37) | | 4 | 3 |
| 2 | NERV | Cerebrovascular accident | | PPD (7) | | PPD (8) | PPD | 2 | 3 |
| 3 | RESP | Respiratory failure | | PPD (34) | | PPD (37) | | 4 | 3 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: Exposed from PPD | 1 | 34 | N |
| 2 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: unknown | 1 | 7 | Y |
| 3 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: Was exposed from PPD | 1 | 34 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| **Narrative Comment** |
|---|
| Participant PPD, a 60-year-old PPD with a pertinent medical history of PPD PPD (unknown dates), PPD (since PPD), and PPD (PPD since PPD), with a BMI of PPD kg/m$^2$ at baseline, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 143).<br><br>Concomitant medications included PPD for PPD PPD for PPD, PPD for PPD and PPD for PPD (unknown dates).<br><br>The participant was diagnosed with a cerebrovascular accident on PPD, 6 days after receiving placebo.<br><br>On PPD (Day 7), the participant woke up in the morning feeling unstable, was staggering, and had slurred speech. PPD presented to the emergency room. The computed tomography scan showed subtle loss of the gray-white matter junction involving the right posterior temporal lobe, concerning for acute infarction with no evidence of acute hemorrhage. Magnetic resonance imaging (MRI) of the brain showed acute infarction in the punctate left pontine perforator with normal intracranial vasculature and an MRI of PPD neck showed no definite flow limiting stenosis of the cervical vasculature per North American Symptomatic Carotid Endarterectomy Trial criteria. The participant's chest x-ray was normal and laboratory results were unremarkable. The participant was hospitalized because of the cerebrovascular accident and treated with PPD. On PPD (Day 8), the cerebrovascular accident resolved, and the participant was discharged from the hospital.<br><br>In the opinion of the investigator, there was no reasonable possibility that the cerebrovascular accident was related to the placebo, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the risk factors, including PPD, provided alternative explanations for the cerebrovascular accident. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 50 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (67) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | METAB | Diabetic ketoacidosis | PPD | PPD (24) | | PPD (26) | | 3 |
| 2 | RESP | Pulmonary embolism | | PPD (21) | | PPD (26) | | 6 |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 3 | TC | N | Resolved (PPD) | NOT RELATED/OTHER: Unknown | 1 | 24 | N |
| 2 | 3 | TC/TCN | Y | Resolved (PPD) | NOT RELATED/OTHER: Unknown | 1 | 21 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 50-year-old PPD with a pertinent medical history of being PPD (since PPD), PPD (in PPD), PPD (since PPD), PPD (since PPD), PPD (since PPD), PPD PPD (since PPD), PPD (since PPD), PPD PPD (since PPD), and PPD, with a BMI of PPD kg/m$^2$ at baseline, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 67).<br><br>Concomitant medications included PPD (since PPD) and PPD (since PPD for PPD, PPD (from PPD to PPD), and PPD (from PPD to PPD) for PPD, and PPD (since PPD) for PPD<br><br>The participant was diagnosed with bilateral pulmonary emboli with symptom onset of PPD, 20 days after receiving placebo.<br><br>On PPD (Day 24), the participant presented to the emergency department with the complaint of shortness of breath for 3 days. The participant continued to complain of chest pressure and was hospitalized. On an unspecified date, an elevated troponin level (value not reported) was noted. On PPD (Day 24), the laboratory test results showed an elevated capillary glucose ranging between 159 mg/dL and 401 mg/dL (normal range [NR]: 70 – 99 mg/dL), hemoglobin A1C of 11.2% (NR: 4.0% - 7.0%), arterial $pO_2$ of 137 mmHg (NR: 80 – 110 mmHg), anion gap of 22 mmol/L (NR: 7 – 15 mmol/L), and ketone (serum beta hydroxybutyrate) of 3.1 mmol/L (NR: not more than 0.4 mmol/L); decreased arterial $pCO_2$ of 30.7 mmHg (NR: 35.0 - 45.0 mmHg), bicarbonate of 14.7 mmol/L (NR: 22.0 - 26.0 mmol/L), carbon dioxide of 12 mmol/L (NR: 22 – 32 mmol/L), arterial base excess of -12.0 mmol/L (lower limit of normal: -2.5 mmol/L); and normal troponin I of 0.35 ng/mL (NR: 0.00 - 0.4 ng/mL). A SARS-CoV-2 test result was negative. A chest x-ray showed no acute pulmonary process. Treatment included PPD for leukocytosis, PPD and PPD for diabetic ketoacidosis. On the same day (Day 24), a |

computed tomography angiography of the chest showed bilateral moderate pulmonary emboli with evidence of mild right heart strain, several pulmonary nodules in the right lung measuring 6 mm in size, moderate wall thickening of the mid to distal thoracic esophagus concerning for acute esophagitis and early emphysema with minimal atelectasis. A pulmonary angiography showed sub massive pulmonary embolism with right ventricular strain. The participant was placed on 2 L oxygen by nasal cannula because of high right heart strain and pulmonary embolus. A computed tomography scan of the abdomen/pelvis with contrast showed bilateral benign peri pelvic cysts vs moderately dilated renal collecting systems although normalizing at the base, and no acute inflammatory processes in the abdomen or pelvis was noted. An electrocardiogram showed sinus tachycardia with a heart rate of 128 beats/min, normal PR and QRS intervals with no notable ST-T changes. On PPD (Day 25), the participant underwent a successful mechanical thrombectomy of bilateral pulmonary artery and its branches. On the same day (Day 25), an echocardiogram showed normal left ventricle systolic function and diastolic function with an estimated ejection fraction of 68%; and the systolic pulmonary arteries peak pressure by Doppler was 47 mmHg. Laboratory test results showed elevated capillary glucose ranging between 111 mg/dL and 212 mg/dL and activated partial thromboplastin time of 55.8 seconds and 46.1 seconds (NR: 25.1 - 36.5 seconds); decreased carbon dioxide ranging between 14 mmol/L and 18 mmol/L; and normal troponin I of 0.15 ng/mL. On PPD (Day 26), the elevated capillary glucose levels ranged between 165 mg/dL and 226 mg/dL. On the same day (Day 26), the pulmonary embolism and diabetic ketoacidosis resolved, and the participant was discharged from the hospital with PPD .

In the opinion of the investigator, there was no reasonable possibility that the bilateral pulmonary emboli were related to the placebo, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the pulmonary embolism was a coincidental medical condition, which was more likely associated with the participant's underlying contributing factors, including PPD , which may cause hypercoagulation.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 70 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (104) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | VASC | Deep vein thrombosis | PPD | PPD (60) | | PPD (61) | | 2 |
| 2 | RESP | Pulmonary embolism | | PPD (60) | | PPD (61) | | 2 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 2 | TC | N | Resolved (PPD) | NOT RELATED/OTHER: unknown | 1 | 60 | Y |
| 2 | 2 | TCN | Y | Resolved (PPD) | NOT RELATED/OTHER: unknown | 1 | 60 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 70-year-old PPD with a pertinent medical history of PPD (since PPD), with a BMI of PPD kg/m$^2$ at baseline, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 104).<br><br>The participant was diagnosed with pulmonary emboli and deep vein thrombosis of the right leg on PPD, 59 days after receiving placebo.<br><br>On PPD (Day 62), the participant reported that PPD was hospitalized on PPD (Day 60) because of bilateral pulmonary emboli. On PPD (Day 60), a chest x-ray was positive for bilateral pulmonary emboli. On PPD (Day 61), the participant underwent a pulmonary angiogram; however, the results were unknown. On the same day (Day 61), the participant underwent a procedure to remove the pulmonary emboli and received PPD That same day (Day 61), treatment with PPD was started, and the pulmonary emboli and deep vein thrombosis were considered resolved. On PPD (Day 62), the participant was discharged from the hospital.<br><br>In the opinion of the investigator, there was no reasonable possibility that the pulmonary emboli were related to the placebo or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.<br><br>In the opinion of the investigator, there was no reasonable possibility that the deep vein thrombosis was related to the placebo. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 70 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |

| Medical History | | | |
|---|---|---|---|
| **Investigator Text** | **MedDRA Preferred Term** | **Start Date** | **Disease Status** |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** |
| 1 | NERV | Cerebrovascular accident | PPD | PPD (166) | | ONGOING | | |
| 2 | GENRL | Injection site erythema | | PPD (2) | | PPD (4) | | 3 |
| 3 | GENRL | Injection site pain | | PPD (1) | PPD | PPD (5) | | 5 |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 3 | N | Y | Yes | NOT RELATED/OTHER: Unknown | 1 | 166 | Y |
| 2 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 3 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 70-year-old PPD with a pertinent medical history of PPD (body mass index of PPD kg/m$^2$ at baseline) and PPD (since PPD), PPD (since PPD), PPD (in PPD), PPD (since PPD), PPD (since PPD), and PPD (since PPD), received BNT162b2 on PPD (Day 1).<br><br>Concomitant medications included PPD (since PPD for PPD PPD (since PPD) for PPD, PPD PPD (both since PPD), PPD (since PPD), and PPD (since PPD) for PPD, PPD (since PPD for PPD, and PPD (since PPD for PPD.<br><br>The participant was diagnosed with a cerebrovascular accident on PPD, 165 days after receiving BNT162b2.<br><br>On PPD (Day 166) the participant experienced neurological dysfunction due to COVID-19 encephalopathy. On the same day (Day 166), a computed tomography (CT) scan of the brain without intravenous contrast showed no acute intercranial abnormality and a COVID-19 polymerase chain reaction test result was positive. On PPD (Day 194), a head CT showed evidence of stroke and the participant was hospitalized on the same day. The participant was discharged from the hospital on an unknown date. The cerebrovascular accident was ongoing at the time of the last available report.<br><br>In the opinion of the investigator, there was no reasonable possibility that the cerebrovascular accident was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 70 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | NERV | Cerebrovascular accident | PPD | PPD (43) | | PPD (71) | | 29 |
| 2 | NERV | Migraine | | PPD (43) | | ONGOING | | |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 3 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: Unknown | 1 | 43 | Y |
| 2 | 3 | TC | N | Yes | NOT RELATED/OTHER: Unknown | 1 | 43 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |

PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_ubBIA/C4591031_6M_Booster_Safety_Narrative/profile. (Cutoff Date: 08FEB2022, Snapshot Date: 03MAR2022) Date of Generation: 24MAR2022 (15:37)

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

**Narrative Comment**

Participant PPD, a 70-year-old PPD with a pertinent medical history of PPD (since PPD; BMI of PPD kg/m$^2$ at baseline), PPD (PPD; from PPD to PPD, and PPD (since PPD), received BNT162b2 on PPD (Day 1).

Concomitant medications included a PPD (since PPD as a supplement, PPD (since PPD for PPD, PPD (since PPD) for PPD, and PPD (since PPD) for PPD.

The participant was diagnosed with a cerebrovascular accident on PPD, 42 days after receiving BNT162b2.

On PPD (Day 57), the participant's PPD called the site and reported that the participant had been experiencing intermittent migraines since PPD (Day 43). The participant did not have a history of migraines. On PPD (Day 45), the participant went to the emergency room for a migraine, and PPD was treated with unknown medications. On PPD (Day 50), the participant again visited the emergency room for a migraine and was treated with unknown medications. On the same day (Day 50), a head magnetic resonance imaging (MRI) was negative for thrombosis. On PPD (Day 51), the participant visited the emergency room for a migraine and was hospitalized. An MRI and computed tomography (CT) scan were performed on an unspecified date in PPD and the results were reported to be normal per PPD. The participant was started on PPD on PPD (Day 51), PPD but subsequently discontinued it because of decreased cognition. PPD was discharged on PPD (Day 52). On PPD (Day 58), the participant experienced a headache and was confused, and was evaluated by a neurologist. The participant was instructed to go to the emergency room and was admitted on PPD (Day 59). The CT and MRI confirmed a stroke with 2 foci detected in the posterior left parietal lobe and posterior right parietal occipital lobes. The symptoms were deemed to be because of reversible cerebral vasoconstriction syndrome but there was no obvious trigger. The participant was placed on PPD and was stable. On PPD (Day 61), an MRI of

the head showed abnormal gyriform restricted diffusion within the bilateral occipital lobes and left parietal lobe with matched fluid-attenuated inversion recovery hyperintense signal abnormality, and the ultrasound scan showed occlusive thrombi in right and left cephalic veins with no evidence of deep vein thrombosis in the lower extremities. On PPD (Day 65), a cerebral angiogram showed diffuse intracerebral beading of the vessels, especially the anterior cerebral artery and middle cerebral artery bilaterally, suggestive of vasculopathy. PPD , with improvement, and on the next day (Day 66), the cerebral angiogram showed mild interval improvement of multiple intracranial arterial stenoses throughout the anterior and posterior circulation with persistent multifocal multivessel intracranial arterial stenoses, wall irregularity and beading, suggestive of vasculopathy. The participant started PPD PPD (since PPD [Day 71]). The cerebrovascular accident resolved on PPD (Day 71) and the participant was discharged from the hospital. The vascular neurologist recommended discharge on PPD with an outpatient follow-up. The acute migraines were ongoing at the time of the last available report.

In the opinion of the investigator, there was no reasonable possibility that the cerebrovascular accident was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 30 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Present |
| | | | Past |
| | | | Past |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | NERV | Seizure | PPD | PPD (23) | | PPD (23) | | 1 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 2 | TC | N | Resolved (PPD) | NOT RELATED/OTHER: previous history | 1 | 23 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 30-year-old PPD with a pertinent medical history of a PPD (in PPD), received BNT162b2 on PPD (Day 1).<br><br>The participant experienced a seizure on PPD, 22 days after receiving BNT162b2.<br><br>Concomitant medication (unspecified) was administered, and the seizure resolved on the same day (Day 23).<br><br>In the opinion of the investigator, there was no reasonable possibility that the seizure was related to BNT162b2, but rather it was related to the medical history of PPD. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | ≤24 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) | Toxicity Grade |
| 1 | NEOPL | Acute lymphocytic leukaemia | PPD | PPD (91) | | ONGOING | | | 3 |
| 2 | NERV | Cerebral haemorrhage | | PPD (110) | | ONGOING | | | 4 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | TC | Y | Yes | NOT RELATED/OTHER: unknown per PI | 1 | 91 | N |
| 2 | TC | Y | Yes | NOT RELATED/OTHER: Unknown at this time awaiting med records | 1 | 110 | Y |

| Prohibited Concomitant Medications | | | | |
|---|---|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date | End Date | Route |
| PPD | | | ONGOING<br>PPD | PPD |

| Prohibited Concomitant Medications | | | | |
|---|---|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date | End Date | Route |
| PPD | | | ONGOING<br>PPD | PPD |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a ≤24-year-old PPD with a pertinent medical history of PPD (since PPD, with a BMI of PPD kg/m$^2$ at baseline, received BNT162b2 on PPD (Day 1).<br><br>The participant was diagnosed with a cerebral hemorrhage on PPD, 109 days after receiving BNT162b2.<br><br>On PPD (Day 78), the participant reported fever, chills, diarrhea, upper abdominal pain, fatigue, decreased appetite, weight loss, and left flank tenderness at a COVID-19 illness visit. The participant's PPD informed the site that the participant had been experiencing severe headaches, vomiting, and pain in muscle/bone for over 30 days, and PPD had been given an injection for headache previously (no further details available), and received PPD The participant was diagnosed with acute lymphocytic leukemia (ALL) on PPD (Day 91), which was considered medically significant. The participant's PPD reported that the chemotherapy was scheduled to commence on PPD (Day 92).<br><br>On PPD (Day 110), the participant had PPD, an episode of left sided paresthesia, and persistent weakness throughout the day, and in the evening, PPD asked PPD for PPD for lower extremity myalgia. However, on the next morning (Day 111), the participant's PPD found the participant unresponsive, without movement on PPD left side, along with right arm jerking. The participant was transferred to the emergency room by an ambulance. A computed tomography (CT) scan of head was performed, which showed a large area of intraparenchymal hemorrhage in the right frontoparietal region measuring up to 7 × 5.1 × 5.2 cm with no definite underlying intraparenchymal lesion; however, there was a 3 cm area of decreased attenuation in the inferior right frontal lobe that was difficult to exclude an underlying brain lesion. Additionally, the superficial cortical veins overlying the right cerebral hemisphere were hyperdense compared to the contralateral side raising the possibility of venous thrombosis. The participant had a consultation with a neurosurgeon who recommended a repeat CT and magnetic resonance imaging (MRI). On PPD (Day 111), the laboratory investigations showed fibrinogen of 34 mg/dL (normal range [NR]: 185-483 mg/dL), D-dimer of 8.16 µg/mL (NR: 0.00-0.49 µg/mL), white blood cell count of 1.6 × 10$^3$/mm$^3$ (NR: 4.0-10.5 × 10$^3$/mm$^3$), red blood cell (RBC) count of 3.5 × 10$^6$/mm$^3$ (NR: 4.10-5.30 × 10$^6$/mm$^3$), platelet count of 103 × 10$^3$/mm$^3$ (NR: 140-440 × 10$^3$/mm$^3$), neutrophil count of 1.28 × 10$^3$/mm$^3$ (NR: 1.8-8.0 × 10$^3$/mm$^3$), lymphocyte percentage of 18% (NR: 25%-45%), hemoglobin of 9.2 g/dL (NR: 12-15 g/dL), hematocrit of 28.6% (NR: 35%-45%), and antithrombin III (ATIII) level of 41% (NR: 80%-120%). On PPD (Day 112), an MRI with and without contrast demonstrated stable hemorrhage and confirmed findings of cortical vein thrombosis as well as a superior sagittal sinus thrombus. The participant was started on maintenance PPD, and a neurologist was consulted. An electroencephalogram (EEG) was performed on PPD (Day 112), which showed right side slowing with no seizure activity. The participant was placed on PPD from PPD (Day 112) to |

PPD (Day 114). On PPD (Day 113), a repeat MRI showed stable hemorrhage and no worsening of venous thrombi. The participant began developing seizure-like activity and the EEG was repeated twice, which showed new signs of focal myoclonic seizures. PPD PPD dose was increased, and in addition, PPD was given a PPD . PPD was then switched to PPD to avoid the liver toxicity associated with PPD . PPD was on PPD from PPD (Day 113) to PPD (Day 116). PPD developed persistent hypertension and required a PPD on PPD (Day 115) and PPD (Day 120). The participant was initiated on feeds of PPD , but given PPD hyperbilirubinemia/hepatitis/cholestasis, this was changed to PPD . However, PPD developed large volume diarrhea on these feeds, so they were discontinued. PPD was again started on PPD from PPD (Day 118). Per gastrointestinal consultation, cholestasis, hyperbilirubinemia, and hepatitis were thought to be due to PPD percutaneous endoscopic gastrostomy asparaginase therapy and PPD was started on PPD . PPD was given prophylactically. A liver ultrasound scan was performed, which showed nonspecific liver enlargement. PPD was discontinued on PPD (Day 120) and PPD feeds were titrated to PPD feeds by PPD (Day 122). A bone marrow biopsy was performed on PPD (Day 120). The participant was given PPD on PPD (Day 120) for chemotherapy prophylaxis. The participant developed oral and "GU" mucositis with ulcers, and a wound culture obtained on PPD (Day 122) grew *Enterococcus faecalis* and *Staphylococcus aureus*. PPD received treatment with PPD . The participant also had a hemorrhoidal and PPD bleed, which developed after starting PPD therapy. Multiple PPD formulations were tried. Bleeding correlated with prolonged partial thromboplastin time and improved when PPD therapy was withheld. The hematology and oncology services were consulted, and the participant received PPD on admission for coagulopathy. PPD per chemotherapy regimen were continued. PPD required 1 unit of platelets on PPD , PPD , and PPD , and required packed RBCs on PPD , PPD , PPD , PPD , PPD , and PPD . PPD continued PPD therapy because of the persistent superior sagittal sinus vein and cortical vein thrombosis. PPD was discontinued and PPD was started on PPD (Day 121). Anti-Xa levels were monitored and PPD dose was adjusted appropriately. The participant was transferred to hematology/oncology services on PPD (Day 123). The participant was naso-duodenal feed dependent. On physical examination, skin breakdown around the perineal and sacral region was noted. The participant also complained of abdominal pain and pain with defecation. PPD also had hemorrhoids. Naso-duodenal feeds of PPD continued. On PPD (Day 126), the participant developed abdominal pain and an abdominal x-ray showed moderate stool burden. PPD was given a PPD and started on PPD and the abdominal pain resolved. Intrathecal chemotherapy was started on PPD (Day 128).

On an unknown date, while the participant's port was being deaccessed, a previous needle site was noted to have dark brown/bloody/pus like drainage. A peripheral intravenous line was placed. An ultrasound was obtained on PPD (Day 132), which demonstrated an

irregular collection measuring 4.3 × 1.3 × 3.3 cm surrounding the port containing echogenic swirling fluid. On PPD (Day 134), the collection at the port site was drained and the samples were sent for culture.

As of the last available report, the participant's last complete blood count was stable with a platelet count of 114000 × $10^3$/$mm^3$ and an anti-Xa level was 0.34 (considered reasonably therapeutic). The liver function remained markedly abnormal. The participant was advised to continue the current line of management, antifungal prophylaxis with PPD, all other supportive care measures, including nursing with frequent change of position. PPD was also advised to continue the same pain PPD PPD and seizure medications, and gastrointestinal protective medications, including PPD, along with PPD for blood pressure control. The plan was to transfer care to a rehabilitation center and continue with nonmyelosuppressive chemotherapy.

The acute lymphocytic leukemia and cerebral hemorrhage were ongoing at the time of the last available report.

In the opinion of the investigator, there was no reasonable possibility that the cerebral hemorrhage was related to BNT162b2. Pfizer concurred with the investigator's causality assessment.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) | Toxicity Grade |
| 1 | CARD | Myocardial infarction | PPD | PPD (64) | PPD | PPD (64) | PPD | 1 | 4 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | TC/TCN | Y | Resolved (PPD) | NOT RELATED/OTHER: Preexisting health condition | 1 | 64 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 60-year-old PPD with a pertinent medical history of PPD (since PPD), received BNT162b2 on PPD (Day 1).<br><br>The participant was diagnosed with a myocardial infarction on PPD, 63 days after receiving BNT162b2.<br><br>On PPD (Day 64), the participant began experiencing extreme chest pain, shortness of breath, left arm pain, nausea, and was fearful. PPD was taken to the emergency room and an electrocardiogram revealed that "PPD was having a heart attack". The participant was admitted for further evaluation. Subsequently, PPD underwent placement of 2 stents at the left anterior descending artery for the myocardial infarction, which was considered life-threatening. PPD was treated with PPD . On the same day (Day 64), the myocardial infarction resolved, and the participant was discharged from the hospital on PPD (Day 66).<br><br>In the opinion of the investigator, there was no reasonable possibility that the myocardial infarction was related to BNT162b2 or clinical trial procedures but was related to a preexisting health condition PPD. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 50 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |

| Medical History | | | |
|---|---|---|---|
| **Investigator Text** | **MedDRA Preferred Term** | **Start Date** | **Disease Status** |
| PPD | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** | **Toxicity Grade** |
| 1 | CARD | Acute myocardial infarction | PPD | PPD (87) | | PPD (94) | | 8 | 4 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: Coronary Artery Disease | 1 | 87 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| **Narrative Comment** |
|---|
| Participant PPD, a 50-year-old PPD with a pertinent medical history of PPD (since PPD, PPD (in PPD), PPD (since PPD, PPD (since PPD, PPD (in PPD, PPD (since PPD), and PPD with a BMI of PPD kg/m$^2$ at baseline, received BNT162b2 on PPD (Day 1).<br><br>Concomitant medications included PPD (since PPD for PPD, PPD (since PPD for PPD, PPD (since PPD) for PPD, PPD (since PPD for PPD, PPD (since PPD) for PPD, and PPD (since PPD) and PPD (since PPD) for PPD.<br><br>The participant was diagnosed with a non-ST elevated acute myocardial infarction on PPD, 86 days after receiving BNT162b2.<br><br>On PPD (Day 87), the participant was reported to have pneumonia and was hospitalized. PPD presented with only symptom of chest tightness. On PPD (Day 88), an electrocardiogram showed sinus rhythm with a heart rate of 83 (unit not reported), normal axis, nondiagnostic ST depression, and V4 and V5 without lateral anterior ST elevation. The participant had a high troponin level of 258 ng/L (normal range: ≤45 ng/L). The participant was treated with PPD. On PPD (Day 92), a SARS-CoV-2 test result was negative. On PPD (Day 94), the non-ST elevated acute myocardial infarction resolved, and the participant was discharged from the hospital.<br><br>In the opinion of the investigator, there was no reasonable possibility that the non-ST elevated acute myocardial infarction was related to BNT162b2, concomitant medications, or clinical trial procedures but was related to the coronary artery disease. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 40 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History |
|---|
| No Medical History |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (53) | PPD |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) | Toxicity Grade | Action to Participant | SAE |
| 1 | EAR | Hypoacusis | PPD | PPD (53) | | PPD (81) | | 29 | 1 | N | N |

| Adverse Events | | | | |
|---|---|---|---|---|
| AE Number | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | Resolved (PPD) | NOT RELATED/OTHER: PT stated symptom after Booster vaccine. However P.I confirms to not related. | 2 | 1 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| Completed | FOLLOW-UP | PPD | |

| Narrative Comment |
|---|
| Participant PPD, a 40 -year-old PPD with no reported medical history, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 53).<br><br>On PPD (Day 53), after receiving BNT162b2, the participant experienced hypoacusis (muffled hearing) which resolved on PPD (Day 81).<br><br>In the opinion of the investigator, there was no reasonable possibility that the hypoacusis was related to BNT162b2. |

| Demography | | | | |
|---|---|---|---|---|
| **Date of Birth** | **Age at Enrollment (Years)** | **Race** | **Ethnicity** | **Sex** |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| **Height** | **Weight** | **BMI** | **Date Collected (Study Day)** |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| **Investigator Text** | **MedDRA Preferred Term** | **Start Date** | **Disease Status** |
| PPD | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (76) | PPD |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | MUSC | Arthritis | PPD | PPD (69) | | ONGOING | | |
| 2 | PSYCH | PPD | | PPD (1) | PPD | PPD (2) | | 2 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 2 | TC | N | Yes | NOT RELATED/OTHER: clinching of teeth | 1 | 69 | Y |
| 2 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 60 -year-old PPD with no pertinent medical history, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 76).<br><br>The participant was diagnosed with arthritis on PPD, 68 days after receiving placebo.<br><br>Concomitant medication (unspecified) was administered, and the arthritis (temporomandibular joint inflammation) was ongoing at the time of the last available report.<br><br>In the opinion of the investigator, there was no reasonable possibility that the arthritis was related to the placebo but was related to clenching of the teeth. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 40 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) | Toxicity Grade |
| 1 | CARD | Myocarditis | PPD | PPD (65) | | PPD (71) | | 7 | 3 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | N | Y | Resolved (PPD) | NOT RELATED/OTHER: Off-study Pfizer Covid-19 vaccine | 1 | 65 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| Withdrawn | FOLLOW-UP | PPD | PROTOCOL DEVIATION |

**Narrative Comment**

Participant PPD, a 40-year-old PPD with a pertinent medical history of PPD (since PPD), with a BMI of PPD kg/m$^2$ at baseline, received placebo on PPD (Day 1).

The participant was diagnosed with myocarditis on PPD, 64 days after receiving placebo.

The participant reported that PPD received an additional (fourth) dose of the Pfizer COVID-19 vaccine on PPD (Day 65), outside of the study. Twelve hours after receiving the fourth dose, the participant experienced severe precordial pain, tachycardia, chest pain, and fever (39ºC). On PPD (Day 69), the participant went to the hospital with these symptoms and was admitted to the intensive care unit with a suspected myocardial infarction. During the hospitalization, the participant's C-reactive protein was 2.98 mg/dL (normal range [NR]: 0.1-0.3 mg/dL) and 1.30 mg/dL on PPD (Day 69) and PPD (Day 70), respectively; a complete blood count on PPD (Day 69) and PPD (Day 70) showed a slight change in lymphocyte count (no values reported). The participant's ultrasensitive troponin was 19 ng/L (NR: upper limit of normal 14 ng/L) and 18 ng/L on PPD (Day 69) and PPD (Day 70), respectively, and troponin level was normal (<0.16 ng/dL, NR: upper limit of normal 0.16 ng/dL) on PPD (Day 70). The coronary angiography performed on PPD (Day 70) and PPD (Day 71) showed normal results. The participant did not take any medications for the symptoms and denied similar episodes in the past.

According to the hospital discharge summary, the participant was discharged from the hospital on PPD (Day 71) without a final diagnosis, and the discharge summary stated that the possible diagnosis was myopericarditis (vaccination reaction). The participant had no history of heart disease and the diagnosis of myopericarditis was made by the team that accompanied the participant to the hospital, based on the temporal relationship with the dose of the nonstudy Pfizer COVID-19 vaccine and the symptoms reported by the participant during hospitalization. On PPD (Day 71), the myocarditis resolved.

The participant had follow-up tests performed, including an ambulatory electrocardiogram on PPD (Day 95), which showed sinus tachycardia and supraventricular extrasystoles, and an echocardiogram on PPD (Day 104), showed ejection fraction of 58% (NR:> 55%); normal or preserved ventricular systolic and diastolic function and presence of "anomalous" movement in the interventricular septum. The participant was waiting for a cardiologist's evaluation. On PPD (Day 125), during a telephone call visit, the participant informed the site that PPD no longer had symptoms of tachycardia and was not using any medication. The participant also stated that PPD had not yet had the cardiology consultation.

In the opinion of the investigator, there was no reasonable possibility that the myocarditis was related to the placebo, but rather it was related to the nonstudy Pfizer COVID-19 vaccine. Pfizer concurred with the investigator's causality assessment. Per Pfizer, there was no reasonable possibility that the myocarditis was related to the clinical trial procedure.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 40 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Present |
| | | | Present |
| | | | Past |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** |
| 1 | NERV | Cerebral venous thrombosis | PPD | PPD (19) | | ONGOING | |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Duration (Days)** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | | 3 | TC | Y | Yes | NOT RELATED/OTHER: Under investigation | 1 | 19 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 40-year-old PPD with a pertinent medical history of PPD (on PPD) and PPD (since PPD), received placebo on PPD (Day 1). The participant had a family history of PPD.<br><br>Concomitant medications included PPD (since PPD for PPD, PPD PPD (since PPD) for PPD, and PPD (since PPD) for headache.<br><br>The participant was diagnosed with a cerebral venous thrombosis on PPD, 18 days after receiving placebo.<br><br>The participant began experiencing headache, nausea, and vomiting on PPD (Day 19). On PPD (Day 22), a computed tomography scan of the head was performed which was suggestive of cerebral venous thrombosis. On the same day (Day 22), a cerebral angiogram confirmed the diagnosis of cerebral venous thrombosis, and the participant was admitted to the intensive care unit. On an unspecified date, the participant's platelet count was normal. The participant was treated with PPD PPD from PPD (Day 22) to PPD (Day 26). On PPD (Day 26), the participant was discharged from the hospital on PPD since PPD (Day 26). The cerebral venous thrombosis was ongoing at the time of the last available report.<br><br>In the opinion of the investigator, there was no reasonable possibility that the cerebral venous thrombosis was related to the placebo, concomitant medications, or clinical trial procedures. Per investigator, the possible cause of the thrombosis was deemed to be thrombocytopenia related to viral vector vaccine; however, the participant had a normal platelet count on an unknown date. The participant's family history of PPD and medical history of PPD, which was confirmed during the hospitalization, were considered contributing factors. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the risk factors for hypercoagulable state including PPD and positive family history of PPD contributed to the thrombotic occurrence. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 50 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time |
| 1 | GENRL | Chills | PPD | PPD (2) | | PPD (3) | |
| 2 | GENRL | Fatigue | | PPD (2) | | PPD (3) | |
| 3 | NERV | Headache | | PPD (2) | | PPD (3) | |
| 4 | GENRL | Injection site pain | | PPD (2) | | PPD (3) | |
| 5 | BLOOD | Lymphadenopathy | | PPD (2) | | PPD (4) | |
| 6 | BLOOD | Lymphopenia | | PPD (4) | | PPD (7) | |
| 7 | BLOOD | Neutropenia | | PPD (4) | | PPD (65) | |
| 8 | BLOOD | Thrombocytopenia | | PPD (4) | | PPD (7) | |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | Duration (Days) | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 2 | 2 | TC | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 2 | 2 | 2 | TC | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 3 | 2 | 2 | TC | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 4 | 2 | 1 | TC | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 5 | 3 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 6 | 4 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 4 | N |
| 7 | 62 | 3 | N | N | Resolved (PPD) | Study Treatment | 1 | 4 | N |
| 8 | 4 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 4 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

**Narrative Comment**

Participant PPD, a 50-year-old PPD with no pertinent medical history, received BNT162b2 on PPD (Day 1).

The participant was diagnosed with thrombocytopenia on PPD, 3 days after receiving BNT162b2.

On PPD (Day 2), the participant experienced chills, fatigue, headache, and injection site pain, which all resolved on PPD (Day 3). The participant also had left axillary lymphadenopathy on PPD (Day 2), which resolved on PPD (Day 4). On the same day (Day 4), the participant had transient lymphopenia, neutropenia, and thrombocytopenia. The transient lymphopenia and thrombocytopenia resolved on PPD (Day 7), and the transient neutropenia resolved on PPD (Day 65). Please see the table below for all the relevant laboratory results:

| Date (Day) | Neutrophils | Lymphocytes | Platelets[a] |
|---|---|---|---|
| PPD (Prior to study entry) | 2440/mm$^3$ (NR: 1700 - 8000/mm$^3$) | 2099/mm$^3$ (NR: 900 - 2900/mm$^3$) | 189,000 (NR: 150,000 - 450,000) |
| PPD (Day 4) | 559/mm$^3$ (NR: 1600 - 7700/mm$^3$) | 822/mm$^3$ (NR: 1000 - 3900/mm$^3$) | 126,000 (NR: 140,000 - 500,000) |
| PPD (Day 7) | 1271/mm$^3$ (NR: 1580 - 7700/mm$^3$) | 1728/mm$^3$ (NR: 740 - 5500/mm$^3$) | 164,000 (NR: 130,000 - 450,000) |
| PPD (Day 65) | 1758/mm$^3$ (NR: 1600-7700/mm$^3$) | - | - |

Abbreviation: NR = normal range.
a. Units not provided.

In the opinion of the investigator, there was a reasonable possibility that the thrombocytopenia was related to BNT162b2.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 40 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |

Reason(s) for Narrative: Adverse Event of Clinical Interest
Participant: PPD; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD; Date of Last Dose: PPD

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) | Toxicity Grade |
| 1 | NERV | Toxic encephalopathy | PPD | PPD (13) | PPD | PPD (30) | PPD | 18 | 3 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | TC | Y | Resolved (PPD) | NOT RELATED/CONCOMITANT DRUG TREATMENT | 1 | 13 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD , a 40 -year-old PPD with a pertinent medical history of PPD (since PPD , PPD (in PPD ), PPD (since PPD ), PPD (since PPD , PPD |

PPD ; in PPD ), PPD (since PPD , PPD (since PPD ), PPD (since PPD , PPD (on PPD ), and PPD (since PPD , received BNT162b2 on PPD (Day 1).

Concomitant medications included PPD (since PPD ) for PPD , PPD (since PPD ) and PPD (since PPD ) for PPD (since PPD ) for PPD , PPD (since PPD ) as a supplement, and PPD (unknown dates) for an unspecified indication.

The participant was diagnosed with toxic encephalopathy (drug-induced metabolic encephalopathy) on PPD , 12 days after receiving BNT162b2.

The participant was seen in PPD on PPD (Day 12). On PPD (Day 13), the participant was found unresponsive in the PPD . PPD showed signs of labored breathing and foot jerking. Emergency medical services arrived, and cardiopulmonary resuscitation was performed on the participant with return of circulation. The participant was intubated in the field and was brought to the emergency department. The etiology for the unresponsiveness was unknown. The participant had acute PPD over the past 24 hours. The laboratory results showed a low calcium level of 8.0 (normal range [NR]: 8.7 - 10.7) and high blood glucose level of 117 (NR: 70 - 99) (units not reported). There was a concern of PPD ; however, the blood test for PPD was within normal range (<10), and PPD to the participant. The examination showed the left pupil at 6 mm and the right pupil at 5 mm (irregular), but they were not reactive to direct light. On the same day (Day 13), a computed tomography scan of the head showed no acute intracranial abnormality. An electroencephalogram (EEG) on an unknown date showed severe diffuse cortical hyperexcitability with increased seizure risk, and the EEG on PPD (Day 16) showed no clear electrographic seizures. The magnetic resonance imaging of the brain without contrast on PPD (Day 17) showed no acute infarction or hemorrhage. A final diagnosis of drug-induced toxic metabolic encephalopathy was made, which was considered as medically significant, and the participant remained intubated until PPD (Day 25) and started on PPD . It was determined that the initial seizure activity was likely caused by drug-induced toxic metabolic encephalopathy. On PPD (Day 30), the toxic encephalopathy resolved, and the participant was discharged from the hospital.

In the opinion of the investigator, there was no reasonable possibility that the toxic encephalopathy was related to BNT162b2, other concomitant medications, or clinical trial procedures, but rather it was related to the PPD Pfizer concurred with the investigator's causality assessment.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 30 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History |
|---|
| No Medical History |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (94) | PPD |

Reason(s) for Narrative: Bell's Palsy
Participant: PPD; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD; Date of Last Dose: PPD

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | NERV | Bell's palsy | PPD | PPD (15) | PPD | PPD (32) | | 18 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 2 | TC | N | Resolved (PPD) | NOT RELATED/OTHER: Viral infection | 1 | 15 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| Withdrawn | FOLLOW-UP | PPD | OTHER |

| Narrative Comment |
|---|
| Participant PPD, a 30 -year-old PPD with no reported medical history, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 94).<br><br>The participant was diagnosed with Bell's palsy (right side) on PPD, 14 days after receiving placebo.<br><br>Concomitant medication (unspecified) was administered, and the Bell's palsy was considered resolved on PPD (Day 32).<br><br>The participant was withdrawn from the study on PPD because they enrolled in Study C4591031 – Substudy D.<br><br>In the opinion of the investigator, there was no reasonable possibility that the Bell's palsy was related to the placebo but was related to a viral infection. |

Reason(s) for Narrative: Appendicitis
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 70 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |





PFIZER CONFIDENTIAL SDTM Creation: 10MAR2022 (02:09) Source Data: dm, vs, mh, ex, ae, cm, ds Output File: ./nda2_ubBIA/C4591031_6M_Booster_Safety_Narrative/profile. (Cutoff Date: 08FEB2022, Snapshot Date: 03MAR2022) Date of Generation: 24MAR2022 (15:37)

Reason(s) for Narrative: Appendicitis
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) | Toxicity Grade |
| 1 | INFEC | Appendicitis perforated | PPD | PPD (70) | PPD | PPD (80) | | 11 | 3 |
| 2 | INFEC | Liver abscess | | PPD (82) | | ONGOING | | | 3 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | TC/TCN | Y | Resolved (PPD) | NOT RELATED/OTHER: appendicitis | 1 | 70 | Y |
| 2 | TC/TCN | Y | Yes | NOT RELATED/OTHER: acute perforated appendix | 1 | 82 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

Reason(s) for Narrative: Appendicitis
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 70-year-old PPD with a pertinent medical history of PPD PPD (since PPD) and PPD (since PPD), with a BMI of PPD kg/m$^2$ at baseline, received BNT162b2 on PPD (Day 1).<br><br>Concomitant medications included PPD (since PPD for PPD, PPD (since PPD) and PPD (since PPD) for PPD, PPD (since PPD) for PPD, PPD (since PPD for PPD, and PPD (since PPD) for PPD.<br><br>The participant was diagnosed with perforated appendicitis on PPD, 69 days after receiving BNT162b2.<br><br>On PPD (Day 68), the participant experienced nausea, vomiting, and headache, and reported a possible COVID-19 illness to the site. A COVID-19 illness visit was scheduled for PPD (Day 70). The participant reported that PPD had already obtained a self-nasal swab test on PPD (Day 70) and a pick-up of the swab was scheduled. The participant did not attend the COVID-19 illness visit on PPD (Day 70) and multiple attempts were made to contact the participant with no success. On the next day (Day 71), the participant's PPD informed the site that the participant went to the emergency room with worsening of nausea and vomiting on PPD (Day 70). A computed tomography (CT) scan of the abdomen showed acute perforated appendicitis and the participant was admitted for emergency surgery. The laboratory results showed a white blood cell (WBC) count of 14.44 k/µL (normal range: 3.98 - 10.04 k/µL). COVID-19 tests performed, including SARS-CoV-2 RNA polymerase chain reaction and SARS-CoV-2 antigen, were both negative. A laparoscopic appendectomy was performed on PPD (Day 70) and the surgical report noted localized peritonitis. A Jackson-Pratt (JP) drain was placed, and the participant was treated with PPD. On PPD (Day 71), the WBC count was within normal range, and the participant was stable on PPD On PPD (Day 72), the participant was stable and discharged home with the JP drain in place and PPD continued as an outpatient. On PPD (Day 77), the participant visited the principal investigator for PPD related to acute perforated appendicitis. The JP drain was removed on the next day (Day 78). On PPD (Day 80), the perforated appendicitis resolved and the PPD was discontinued.<br><br>On PPD (Day 82), the participant experienced right upper quadrant and flank pain associated with increasing diarrhea, and PPD visited the emergency room on PPD (Day 83). A CT scan of the abdomen and pelvis showed a right hepatic lesion concerning for an abscess. PPD was treated with PPD, which was later switched to PPD. An |

ultrasound-guided drainage of the abscess was performed on PPD (Day 84). The participant's PPD were changed to PPD. The participant was stable and discharged on PPD (Day 85) with an instruction to continue PPD as an outpatient. However, on PPD (Day 89), the participant had re-accumulation of hepatic abscess (reported as re-accumulation of hepatic fluid collection that was previously drained), which was treated with PPD. The liver abscess was ongoing at the time of the last available report.

In the opinion of the investigator, there was no reasonable possibility that the perforated appendicitis was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. Per Pfizer, the perforated appendicitis was more likely a coincidental infectious condition.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 50 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |

Reason(s) for Narrative: Appendicitis
Participant: PPD; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD; Date of Last Dose: PPD

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | INFEC | Appendicitis | PPD | PPD (95) | PPD | PPD (96) | PPD | 2 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 3 | N | Y | Resolved (PPD) | NOT RELATED/OTHER: idiopathic | 1 | 95 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| | TREATMENT UNBLINDED | | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 50-year-old PPD with a pertinent medical history of PPD (in PPD, PPD (on PPD), PPD (in PPD), and PPD PPD (since PPD), with a BMI of PPD kg/m$^2$ at baseline, received BNT162b2 on PPD (Day 1).<br><br>Concomitant medications included PPD (since PPD) and PPD (since PPD) for PPD, PPD (since PPD) for PPD, PPD (since PPD) and PPD (since PPD) for PPD, and PPD (since PPD for PPD.<br><br>The participant was diagnosed with appendicitis on PPD, 94 days after receiving BNT162b2.<br><br>During the telephone contact visit, the participant reported that PPD went to the emergency room on PPD (Day 95) because of severe lower abdominal pain. PPD white blood cell count was 12.1 × 10$^3$/µL (normal range: 3.7-10.3 × 10$^3$/µL) and a computed tomography scan of the abdomen and pelvis showed a rounded inflamed structure projecting off the medial inferior aspect of the cecum measuring up to 2.7 cm in diameter, which was compatible with acute appendicitis, associated with adjacent fat stranding and inflammatory changes. The rounded configuration of the inflamed appendix might be due to the inflamed appendix being folded upon itself although a contained perforation could not be excluded. However, there was no evidence of discrete abscess or free intraperitoneal air. The participant was treated with PPD and underwent an emergency laparoscopic appendectomy. On PPD (Day 96), the participant recovered from the appendicitis and was discharged from the hospital on PPD A final diagnosis of acute appendicitis with periappendicitis and periappendiceal fibrosis was made based on the pathology report received on PPD (Day 126).<br><br>In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | ≥75 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |

Reason(s) for Narrative: Appendicitis
Participant: PPD; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD; Date of Last Dose: PPD

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | INFEC | Abscess | PPD | PPD (59) | | ONGOING | | |
| 2 | INFEC | Appendicitis | | PPD (50) | | PPD (51) | | 2 |
| 3 | INFEC | Appendicitis perforated | | PPD (50) | | PPD (51) | | 2 |
| 4 | NEOPL | Follicular lymphoma | | PPD (39) | | ONGOING | | |
| 5 | VASC | Haematoma | | PPD (51) | | ONGOING | | |
| 6 | METAB | Hyponatraemia | | PPD (51) | | PPD (55) | | 5 |
| 7 | GASTR | Inguinal hernia | | PPD (51) | | ONGOING | | |
| 8 | INV | Lipase increased | | PPD (51) | | ONGOING | | |

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**Reason(s) for Narrative: Appendicitis**
**Participant:** PPD **; Country:** PPD
**Vaccine Group (as Administered): BNT162b2 (30 µg)**
**Date of First Dose:** PPD **; Date of Last Dose:** PPD

==========

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** |
| 9 | INFEC | Peritonitis | PPD | PPD (51) | | PPD (51) | | 1 |
| 10 | RENAL | Renal cyst | | PPD (51) | | ONGOING | | |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 2 | N | N | Yes | NOT RELATED/OTHER: peritonitis | 1 | 59 | N |
| 2 | 3 | TC/TCN | Y | Resolved (PPD) | NOT RELATED/OTHER: Unknown | 1 | 50 | Y |
| 3 | 3 | N | N | Resolved (PPD) | NOT RELATED/OTHER: acute appendicitis | 1 | 50 | Y |
| 4 | 3 | N | Y | Yes | NOT RELATED/OTHER: unknown | 1 | 39 | N |
| 5 | 2 | N | N | Yes | NOT RELATED/OTHER: previous surgeries | 1 | 51 | N |
| 6 | 1 | N | N | Resolved (PPD) | NOT RELATED/OTHER: unknown | 1 | 51 | N |
| 7 | 2 | N | N | Yes | NOT RELATED/OTHER: anatomical defect | 1 | 51 | N |
| 8 | 2 | N | N | Yes | NOT RELATED/OTHER: unknown | 1 | 51 | N |
| 9 | 3 | N | N | Resolved (PPD) | NOT RELATED/OTHER: appendicitis | 1 | 51 | N |
| 10 | 1 | N | N | Yes | NOT RELATED/OTHER: unknown | 1 | 51 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| **Narrative Comment** |
|---|
| Participant PPD, an ≥75-year-old PPD with a pertinent medical history of PPD (since PPD), PPD (since PPD, PPD (since PPD), PPD (since PPD, and PPD (on PPD), received BNT162b2 on PPD (Day 1).<br><br>Concomitant medications included PPD (since PPD) for PPD, PPD (since PPD for PPD PPD, PPD (since PPD for PPD, and PPD (since PPD) for PPD.<br><br>On PPD, one week prior to study entry, the participant underwent PPD The pathology results showed melanoma, superficial spreading type, invasive to a depth of 0.8 mm. The participant consulted an oncologist, and a biopsy of the right axillary lymph node was taken. The overall histopathology findings were consistent with grade 1-2 follicular lymphoma (which was ongoing since PPD [Day 39]). There was no evidence of metastatic melanoma.<br><br>The participant was diagnosed with acute appendicitis with a perforated appendix on PPD, 49 days after receiving BNT162b2.<br><br>On PPD (Day 50), the participant presented to the emergency room with right lower quadrant pain that increased throughout the day. The participant was hospitalized on the same day (Day 50). On PPD (Day 51), an abdominal ultrasound showed a 7.8 ×3.1 × 2.6 cm ovoid peripherally calcified fluid collection possibly reflecting a chronic hematoma, as well as a dilated fluid filled tubular structure, suspicious for acute appendicitis. The computed tomography (CT) scan with contrast of the abdomen and pelvis showed hazy inflammatory changes surrounding a dilated appendix consistent with acute appendicitis with no abscess identified. A fluid filled tubular structure measuring 3 × 7 cm in the right hemipelvis appeared to be benign and suspected to be a remote hematoma. The laboratory investigations showed elevated lipase of 237 U/L (normal range: 0 – 160 U/L), an elevated white blood cell count, mild anemia with normal platelets, and mild hyponatremia (values not reported). The physical examination was consistent with right lower quadrant peritonitis. On PPD (Day 51), the participant underwent a laparoscopic appendectomy without any complications. The surgery notes indicated that there was significant injection of the peritoneum with frank purulence in the pelvis and the right lower quadrant; a total of 150 mL of pus was aspirated.<br><br>There was fecal contamination in the right lower quadrant as there was a perforation just distal to the base of the appendix. No fluid culture was performed. The participant was treated with PPD PPD (Day 51). The acute appendicitis, perforated appendicitis, and peritonitis resolved on |

PPD (Day 51). On PPD (Day 55), the hyponatremia resolved, and the participant was treated with PPD PPD and was discharged from the hospital. The hematoma and increased lipase were ongoing at the time of the last available report.

In the opinion of the investigator, there was no reasonable possibility that the acute appendicitis was related to BNT162b2, concomitant medications, or clinical trial procedures. Pfizer concurred with the investigator's causality assessment.

In the opinion of the investigator, there was no reasonable possibility that the perforated appendix was related to BNT162b2.

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 50 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** | **Toxicity Grade** |
| 1 | INFEC | Appendicitis | PPD | PPD (186) | | PPD (190) | | 5 | 3 |
| 2 | NERV | Headache | | PPD (1) | PPD | PPD (2) | PPD | 2 | 1 |
| 3 | GENRL | Injection site pain | | PPD (1) | PPD | PPD (2) | PPD | 2 | 1 |
| 4 | INFEC | Peritonitis | | PPD (189) | | PPD (190) | | 2 | 3 |
| 5 | INJ&P | Procedural nausea | | PPD (189) | | PPD (190) | | 2 | 2 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | TC/TCN | Y | Resolved (PPD) | NOT RELATED/OTHER: Bacterial infection of abdomen and appendix | 1 | 186 | Y |
| 2 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 3 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 4 | TC/TCN | Y | Resolved (PPD) | NOT RELATED/OTHER: Appendicitis | 1 | 189 | N |
| 5 | TC | N | Resolved (PPD) | NOT RELATED/OTHER: anesthetic and surgical effects | 1 | 189 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 50-year-old PPD with a pertinent medical history of PPD PPD (on PPD), received BNT162b2 on PPD (Day 1).<br><br>The participant was diagnosed with appendicitis on PPD, 185 days after receiving BNT162b2.<br><br>On PPD (Day 188), the participant experienced epigastric pain for about 2 days. The pain, mostly felt in the right lower quadrant, was unrelenting and the participant was unable to eat. PPD denied nausea. On the same day (Day 188), the laboratory results showed a white blood cell (WBC) count of 12.8 x $10^3$/$mm^3$ (normal range [NR]: 3.7-10.5 x $10^3$/$mm^3$); gamma-glutamyl transferase of 67 IU/L (NR: 5-36 IU/L); and a urinalysis showed traces of blood and ketones and leukocyte esterase of 1+. On PPD (Day 189), the participant presented to the emergency department for evaluation of the right lower quadrant pain. On the same day (Day 189), a computed tomography scan of the abdomen and pelvis with contrast showed a dilated appendix with fat stranding and acute uncomplicated appendicitis with mesenteric fat stranding and several appendicoliths. No periappendiceal abscess was observed. An abdominal ultrasound showed findings consistent with acute appendicitis with possible perforation. The participant had leukocytosis (WBC count was 12000; unit and NR not reported). On PPD (Day 189), the participant underwent a laparoscopic appendectomy with findings of inflamed appendicitis with murky ascites in the pelvis without obvious perforation. Post-surgery, the participant was admitted to the hospital. The participant experienced postoperative nausea and generalized peritonitis. During hospitalization, the participant was treated with PPD. The participant was tolerating the diet very well without nausea or vomiting. On PPD (Day 190), the participant's WBC count was 13.4 x $10^3$/$mm^3$. On the same day (Day 190), the appendicitis, generalized peritonitis, and postoperative nausea were considered resolved, and the participant was discharged from the hospital.<br><br>In the opinion of the investigator, there was no reasonable possibility that the appendicitis was related to BNT162b2 or clinical trial procedures but was related to a bacterial infection of the abdomen and appendix. Pfizer concurred with the investigator's causality assessment. |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 30 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (91) | PPD |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** | **Toxicity Grade** |
| 1 | MUSC | Back pain | PPD | PPD (2) | PPD | PPD (3) | PPD | 2 | 1 |
| 2 | GENRL | Chills | | PPD (92) | PPD | PPD (92) | PPD | 1 | 1 |
| 3 | INJ&P | PPD | | PPD (112) | | ONGOING | | | |
| 4 | NERV | Headache | | PPD (2) | PPD | PPD (3) | PPD | 2 | 1 |
| 5 | NERV | Headache | | PPD (92) | PPD | PPD (92) | PPD | 1 | 1 |
| 6 | VASC | Hot flush | | PPD (1) | PPD | PPD (2) | PPD | 2 | 1 |
| 7 | GENRL | Injection site pain | | PPD (1) | PPD | PPD (2) | PPD | 2 | 1 |
| 8 | GENRL | Injection site pain | | PPD (91) | PPD | PPD (96) | PPD | 6 | 1 |
| 9 | GASTR | Nausea | | PPD (92) | PPD | PPD (92) | PPD | 1 | 1 |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 2 | TC | N | Resolved (PPD) | Study Treatment | 2 | 2 | N |
| 3 | N | N | Yes | NOT RELATED/OTHER: PPD | 2 | 22 | Y |
| 4 | N | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 5 | N | N | Resolved (PPD) | Study Treatment | 2 | 2 | N |
| 6 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 7 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |

Reason(s) for Narrative: PPD
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 8 | TC | N | Resolved (PPD) | Study Treatment | 2 | 1 | N |
| 9 | TC | N | Resolved (PPD) | Study Treatment | 2 | 2 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |

Reason(s) for Narrative: PPD
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| PPD |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 30 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (112) | PPD |

Reason(s) for Narrative: PPD
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time |
| 1 | PSYCH | PPD | PPD | PPD (8) | | ONGOING | |
| 2 | INJ&P | | | PPD (137) | | ONGOING | |
| 3 | GASTR | Nausea | | PPD (137) | | ONGOING | |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | Duration (Days) | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | | 2 | TC | N | Yes | NOT RELATED/OTHER: PPD | 1 | 8 | N |
| 2 | | | TC | N | Yes | NOT RELATED/OTHER: | 2 | 26 | Y |
| 3 | | 2 | TC | N | Yes | NOT RELATED/OTHER: | 2 | 26 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

Reason(s) for Narrative: PPD
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

Reason(s) for Narrative: PPD
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Narrative Comment |
| --- |
| PPD |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 40 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Past |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (121) | PPD |

Reason(s) for Narrative: PPD
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | PPD | | PPD | PPD (59) | | PPD (59) | | 1 |
| 2 | INJ&P | PPD | | PPD (10) | | PPD (59) | | 50 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | | TCN | Y | Resolved (PPD) | NOT RELATED/OTHER: PPD | 1 | 59 | N |
| 2 | | N | N | Resolved (PPD) | NOT RELATED/OTHER: Unknown | 1 | 10 | Y |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

Reason(s) for Narrative: PPD
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

Reason(s) for Narrative: PPD
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Narrative Comment |
| --- |
| PPD |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 40 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Past |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

**Adverse Events**

| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) | Toxicity Grade |
|---|---|---|---|---|---|---|---|---|---|
| 1 | PPD | | PPD | PPD (57) | | PPD (57) | | 1 | 2 |
| 2 | GENRL | Chills | | PPD (2) | | PPD (4) | | 3 | 3 |
| 3 | INJ&P | PPD | | PPD (9) | | PPD (57) | | 49 | |
| 4 | NERV | Headache | | PPD (2) | | PPD (4) | | 3 | 3 |
| 5 | GENRL | Injection site pain | | PPD (2) | | PPD (4) | | 3 | 3 |
| 6 | REPRO | PPD | | PPD (3) | | PPD (7) | | 5 | 1 |
| 7 | MUSC | Myalgia | | PPD (2) | | PPD (4) | | 3 | 3 |
| 8 | GENRL | Pyrexia | | PPD (2) | | PPD (4) | | 3 | 3 |
| 9 | NEOPL | PPD | | PPD (31) | | ONGOING | | | 2 |

**Adverse Events**

| AE Number | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
|---|---|---|---|---|---|---|---|
| 1 | N | Y | Resolved (PPD) | NOT RELATED/OTHER:PPD | 1 | 57 | N |
| 2 | TC | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 3 | N | N | Resolved (PPD) | NOT RELATED/OTHER: PPD | 1 | 9 | Y |
| 4 | TC | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 5 | TC | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 6 | N | N | Resolved (PPD) | NOT RELATED/OTHER: leiomyomatosis | 1 | 3 | N |
| 7 | TC | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 8 | TC | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 9 | N | N | Yes | NOT RELATED/OTHER: Possibly related to the PPD | 1 | 31 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

Reason(s) for Narrative: PPD
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Narrative Comment |
| --- |
| PPD |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History |
|---|
| No Medical History |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events |
|---|
| No Adverse Events |

| Adverse Events |
|---|
| No Adverse Events |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Date of Collection (Study Day)** | **Specimen Type** | **Test Result** |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |

| Case Details | | |
|---|---|---|
| **Visit** | **>7 Days After Booster** | **Severe** |
| COVID Illness Visit 1 | Yes | No |
| COVID Illness Visit 2 | Yes | No |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| **Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing** | **Prespecified Event** | **Symptoms (Prespecified and Others)** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 / PPD (162)/ PPD (161)/ PPD (170) | NO | | Rhinorrhoea |
| | YES | NEW OR INCREASED COUGH | |
| COVID Illness Visit 2 / PPD (188)/ PPD (185)/ PPD (196) | NO | | Sinus congestion |
| | YES | NEW OR INCREASED COUGH | |
| | NO | | Headache |

| Diagnosis of Potential COVID-19 Illness |
|---|
| No Diagnosis of Potential COVID-19 Illness |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| 1 | COVID Illness Visit 1 | PPD (162) | PPD (162) | SWABBED MATERIAL | POSITIVE |
| 2 | COVID Illness Visit 2 | PPD (188) | PPD (187) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory |
|---|
| No SARS-COV-2 Test - Local Laboratory |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (162) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 2 | PPD (188) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details |
|---|
| No Hospitalization Details |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry |
|---|
| No Laboratory Results - Clinical Chemistry |

| Laboratory Results - Hematology |
|---|
| No Laboratory Results - Hematology |

| Vital Signs - COVID-19 |
|---|
| No Vital Signs - COVID-19 |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging |
|---|
| No Imaging |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 60 -year-old PPD with a BMI of PPD kg/m$^2$, received BNT162b2 on PPD (Day 1).<br><br>The participant had no reported medical history.<br><br>The central laboratory SARS-CoV-2 NAAT and N-binding antibody results were negative at Visit 1.<br><br>On PPD (Day 162), the participant reported rhinorrhea and new or increased cough, with the first symptom starting on PPD, 160 days after receiving BNT162b2, and the last symptom resolved on PPD (Day 170).<br><br>The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on PPD (Day 162) was positive. No local laboratory SARS-CoV-2 NAAT was done.<br><br>On PPD (Day 188), the participant reported sinus congestion, headache, and new or increased cough, with the first symptom starting on PPD, 184 days after receiving BNT162b2, and the last symptom resolved on PPD (Day 196).<br><br>The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on PPD (Day 187) was positive. No local laboratory SARS-CoV-2 NAAT was done.<br><br>The participant did not have any contact with nonstudy healthcare personnel (at COVID-19 illness visits 1 and 2). |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Past |

Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (85) | PPD |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** |
| 1 | GENRL | Injection site pain | PPD | PPD (86) | | PPD (87) | |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Duration (Days)** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 2 | 1 | N | N | Resolved (PPD) | Study Treatment | 2 | 2 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Date of Collection (Study Day)** | **Specimen Type** | **Test Result** |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |
| Visit 2 | PPD (85) | PPD (85) | SWABBED MATERIAL | NEGATIVE |
| Visit 2 | PPD (85) | PPD (85) | SERUM | NEGATIVE |

| Case Details | | |
|---|---|---|
| **Visit** | **>7 Days After Booster** | **Severe** |
| COVID Illness Visit 1 | Yes | No |
| COVID Illness Visit 2 | Yes | No |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| **Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing** | **Prespecified Event** | **Symptoms (Prespecified and Others)** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 / PPD (162)/ PPD (157)/ PPD (160) | YES | NEW OR INCREASED COUGH | |
| COVID Illness Visit 2 / PPD (171)/ PPD (171)/ PPD (177) | YES | NEW OR INCREASED MUSCLE PAIN | |
| | YES | NEW OR INCREASED COUGH | |
| | YES | DIARRHEA | |

| Diagnosis of Potential COVID-19 Illness | | | | | |
|---|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Respiratory Illness Diagnosis** | **Date of Diagnosis (Study Day)** | **Toxicity Grade** | **MedDRA Preferred Term** |
| COVID Illness Visit 2 | PPD (171) | COVID-19 | PPD (174) | 1 | COVID-19 |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| 1 | COVID Illness Visit 1 | PPD (162) | PPD (163) | SWABBED MATERIAL | POSITIVE |
| 2 | COVID Illness Visit 2 | PPD (171) | PPD (171) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory | | | | |
|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type |
| 1 | COVID Illness Visit 2 | PPD (171) | PPD (174) | SWABBED MATERIAL |

| SARS-COV-2 Test - Local Laboratory | | | | |
|---|---|---|---|---|
| Lab Test Number | Specimen Collection Location | Test Result | Comments/Findings/Details | Trade Name |
| 1 | NASOPHARYNX | POSITIVE | Unknown PCR test | NALT Unknown |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (162) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |
| COVID Illness Visit 2 | PPD (171) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | YES | 1 | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details |
|---|
| No Hospitalization Details |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry |
|---|
| No Laboratory Results - Clinical Chemistry |

| Laboratory Results - Hematology |
|---|
| No Laboratory Results - Hematology |

| Vital Signs - COVID-19 |
|---|
| No Vital Signs - COVID-19 |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging |
|---|
| No Imaging |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 60-year-old PPD with a BMI of PPD kg/m$^2$, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 85).<br><br>The participant had a pertinent medical history of PPD (since PPD .<br><br>The central laboratory SARS-CoV-2 NAAT and N-binding antibody results were negative at Visit 1 and Visit 2.<br><br>On PPD (Day 162), the participant reported new or increased cough, with the symptom starting on PPD, 72 days after receiving BNT162b2, that resolved on PPD (Day 160).<br><br>The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on PPD (Day 163) was positive. No local laboratory SARS-CoV-2 NAAT was done.<br><br>The participant did not have any contact with nonstudy healthcare personnel (at COVID-19 illness visit 1).<br><br>On PPD (Day 174), the participant was diagnosed with COVID-19 and reported new or increased muscle pain, new or increased cough, and diarrhea, with the first symptom starting on PPD, 86 days after receiving BNT162b2, and the last symptom resolved on PPD (Day 177).<br><br>The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on PPD (Day 171) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on PPD (Day 174) was positive.<br><br>The participant went to PPD primary care physician (once) (at COVID-19 illness visit 2). |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (97) | PPD |

| Adverse Events |
|---|
| No Adverse Events |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |
| Visit 2 | PPD (97) | PPD (97) | SWABBED MATERIAL | NEGATIVE |
| Visit 2 | PPD (97) | PPD (97) | SERUM | NEGATIVE |

| Case Details | | |
|---|---|---|
| Visit | >7 Days After Booster | Severe |
| COVID Illness Visit 1 | Yes | Yes |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing | Prespecified Event | Symptoms (Prespecified and Others) | MedDRA Preferred Term |
| COVID Illness Visit 1 / PPD (169)/ PPD (167)/ ONGOING | YES | NEW OR INCREASED SORE THROAT | |
| | YES | NEW OR INCREASED COUGH | |

| Diagnosis of Potential COVID-19 Illness | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Respiratory Illness Diagnosis | Date of Diagnosis (Study Day) | Toxicity Grade | MedDRA Preferred Term |
| COVID Illness Visit 1 | PPD (169) | SARS-CoV-2 positive test result | PPD (168) | 1 | SARS-CoV-2 test positive |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| 1 | COVID Illness Visit 1 | PPD (169) | PPD (169) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory |
|---|
| No SARS-COV-2 Test - Local Laboratory |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (169) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | YES | 1 | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details |
|---|
| No Hospitalization Details |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry |
|---|
| No Laboratory Results - Clinical Chemistry |

| Laboratory Results - Hematology |
|---|
| No Laboratory Results - Hematology |

**Vital Signs - COVID-19**

| Visit | Visit Date (Study Day) | Date Collected (Study Day) | Record Identifier | Systolic Blood Pressure | Diastolic Blood Pressure | Respiratory Rate | Heart Rate | Oxygen Saturation |
|---|---|---|---|---|---|---|---|---|
| COVID Illness Visit 1 | PPD (169) | PPD (169) | 1 | 104 mmHg | 57 mmHg | 18 breaths/min | 67 beats/min | 97 % |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging |
|---|
| No Imaging |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 60 -year-old PPD with a BMI of PPD kg/m$^2$, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 97).<br><br>The participant had no pertinent medical history.<br><br>The central laboratory SARS-CoV-2 NAAT and N-binding antibody results were negative at Visit 1 and Visit 2.<br><br>On PPD (Day 168), the participant had a positive SARS-CoV-2 test result and reported new or increased sore throat and new or increased cough, with the first symptom starting on PPD, 70 days after receiving BNT162b2, and at least 1 symptom was ongoing as of the last available report.<br><br>The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on PPD (Day 169) was positive. No local laboratory SARS-CoV-2 NAAT was done.<br><br>The participant went to PPD primary care physician (once).<br><br>On PPD (Day 169), the participant had a blood pressure of 104/57 mm Hg, heart rate of 67 beats/min, respiratory rate of 18 breaths/min, and oxygen saturation of 97% on room air.<br><br>The participant therefore had severe COVID-19 illness per protocol criteria (ie, confirmed COVID-19 and diastolic blood pressure <60 mm Hg). |

| Demography | | | | |
|---|---|---|---|---|
| **Date of Birth** | **Age at Enrollment (Years)** | **Race** | **Ethnicity** | **Sex** |
| PPD | 70 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| **Height** | **Weight** | **BMI** | **Date Collected (Study Day)** |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| **Investigator Text** | **MedDRA Preferred Term** | **Start Date** | **Disease Status** |
| PPD | | | Past |
| | | | Past |
| | | | Present |
| | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time | Duration (Days) |
| 1 | NERV | Cerebrovascular accident | PPD | PPD (166) | | ONGOING | | |
| 2 | GENRL | Injection site erythema | | PPD (2) | | PPD (4) | | 3 |
| 3 | GENRL | Injection site pain | | PPD (1) | PPD | PPD (5) | | 5 |

Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 3 | N | Y | Yes | NOT RELATED/OTHER: Unknown | 1 | 166 | N |
| 2 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 3 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |

| Case Details | | |
|---|---|---|
| Visit | >7 Days After Booster | Severe |
| COVID Illness Visit 1 | Yes | Yes |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing | Prespecified Event | Symptoms (Prespecified and Others) | MedDRA Preferred Term |
| COVID Illness Visit 1 / PPD (155)/ PPD (131)/ ONGOING | NO | | Upper-airway cough syndrome |
| | NO | | Nasal congestion |
| | YES | NEW OR INCREASED SHORTNESS OF BREATH | |
| | YES | NEW OR INCREASED COUGH | |

| Diagnosis of Potential COVID-19 Illness | | | | | |
|---|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Respiratory Illness Diagnosis** | **Date of Diagnosis (Study Day)** | **Toxicity Grade** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 | PPD (155) | COVID-19 Illness | PPD (166) | 3 | COVID-19 |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| **Lab Test Number** | **Visit** | **Visit Date (Study Day)** | **Date of Collection (Study Day)** | **Specimen Type** | **Test Result** |
| 1 | COVID Illness Visit 1 | PPD (155) | PPD (172) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory | | | | |
|---|---|---|---|---|
| **Lab Test Number** | **Visit** | **Visit Date (Study Day)** | **Date of Collection (Study Day)** | **Specimen Type** |
| 1 | COVID Illness Visit 1 | PPD (155) | PPD (166) | SWABBED MATERIAL |

| SARS-COV-2 Test - Local Laboratory | | | | |
|---|---|---|---|---|
| Lab Test Number | Specimen Collection Location | Test Result | Comments/Findings/Details | Trade Name |
| 1 | NASOPHARYNX | POSITIVE | | NALT - Unknown |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (155) | OTHER | YES | | HOSPITAL |
| | | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | YES | 1 | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | YES | 1 | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Hospitalization Category | Hospitalization Term | Admission Date (Study Day) | Discharge Date or Ongoing (Study Day) |
| COVID Illness Visit 1 | PPD (155) | HOSPITALIZATION STATUS | HOSPITAL | PPD (166) | PPD (169) |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

**Laboratory Results - Clinical Chemistry**

| Visit | Visit Date (Study Day) | Date of Test (Study Day) | Laboratory Test | Result | Units | Lower Limit Range | Upper Limit Range |
|---|---|---|---|---|---|---|---|
| COVID Illness Visit 1 | PPD (155) | PPD (166) | Alkaline Phosphatase | 1.5 | ukat/L | 0.67 | 2.15 |
| | | PPD (166) | Alanine Aminotransferase | 0.28339 | ukat/L | 0.11669 | 0.91685 |
| | | PPD (166) | Aspartate Aminotransferase | 0.41675 | ukat/L | 0.13336 | 0.80016 |
| | | PPD (166) | Bilirubin | 6.8 | umol/L | . | 20.5 |
| | | PPD (166) | Creatinine | 89.3 | umol/L | 65.4 | 119.3 |
| | | PPD (166) | C Reactive Protein | 86 | mg/L | . | 80 |
| | | PPD (166) | Urea Nitrogen | 4.64 | mmol/L | 2.86 | 8.57 |

| Laboratory Results - Hematology | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Date of Test (Study Day)** | **Laboratory Test** | **Result** | **Units** | **Lower Limit Range** | **Upper Limit Range** |
| COVID Illness Visit 1 | PPD (155) | PPD (166) | Basophils | UNCONVERTED | 10^9/L | 0 | 2 |
| | | PPD (166) | Eosinophils | UNCONVERTED | 10^9/L | 1 | 3 |
| | | PPD (166) | Hematocrit | 0.38 | L/L | 0.38 | 0.48 |
| | | PPD (166) | Hemoglobin | 117 | g/L | 132 | 166 |
| | | PPD (166) | Lymphocytes | UNCONVERTED | 10^9/L | 18 | 42 |
| | | PPD (166) | Monocytes | UNCONVERTED | 10^9/L | 2 | 11 |
| | | PPD (166) | Neutrophils | 6.83 | 10^9/L | 1.56 | 6.45 |
| | | PPD (166) | Platelets | 247 | 10^9/L | 135 | 317 |
| | | PPD (166) | Erythrocytes | 4.87 | 10^12/L | 4.3 | 5.65 |
| | | PPD (166) | Leukocytes | 8 | 10^9/L | 3.4 | 9.6 |

| Vital Signs - COVID-19 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Date Collected (Study Day)** | **Record Identifier** | **Systolic Blood Pressure** | **Diastolic Blood Pressure** | **Respiratory Rate** | **Heart Rate** | **Oxygen Saturation** |
| COVID Illness Visit 1 | PPD (155) | PPD (166) | 1 | 176 mmHg | 78 mmHg | 25 breaths/min | 94 beats/min | 95 % |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Assessment Number** | **Visit** | **Visit Date (Study Day)** | **Date of Assessment** | **Location of Assessment** | **If Other, Specify** | **Type of Imaging Exam** | **If Other, Specify** |
| 1 | COVID Illness Visit 1 | PPD (155) | PPD | CHEST | | X-RAY | NA |
| 2 | COVID Illness Visit 1 | PPD (155) | PPD | HEAD | | CT SCAN | NA |

| Imaging | | |
|---|---|---|
| **Assessment Number** | **Overall Assessment** | **If Abnormal, Specify Findings** |
| 1 | ABNORMAL | No focal consolidation. Stable cardiomegaly with mildly increased interstitial markings likely reflect mild interstitial edema. |
| 2 | NORMAL | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| **Narrative Comment** |
|---|
| Participant PPD, a 70-year-old PPD with a BMI of PPD kg/m$^2$, received BNT162b2 on PPD (Day 1).<br><br>The participant had a pertinent medical history of PPD (since PPD, PPD (since PPD), PPD PPD (since PPD), PPD (since PPD), and PPD (since PPD).<br><br>The central laboratory SARS-CoV-2 NAAT and N-binding antibody results were negative at Visit 1.<br><br>On PPD (Day 166), the participant was diagnosed with severe COVID-19 and reported nasal congestion, upper-airway cough syndrome, new or increased shortness of breath, and new or increased cough, with the first symptom starting on PPD, 130 days after receiving BNT162b2, and at least 1 symptom was ongoing as of the last available report.<br><br>The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on PPD (Day 166) was positive. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on PPD (Day 172) was positive.<br><br>On PPD (Day 166), the participant had a heart rate of 94 beats/min, blood pressure of 176/78 mm Hg, respiratory rate of 25 breaths/min, and oxygen saturation of 95% on room air.<br><br>On PPD (Day 166), a chest radiograph revealed no focal consolidation, stable cardiomegaly with mildly increased interstitial markings, suggestive of mild interstitial edema and a computed tomographic (CT) scan of the head was normal. On the same day (Day 166), the laboratory results showed an elevated C-reactive protein level of 86 mg/L (normal range [NR]: <80 mg/L) and neutrophils of 6.83 × $10^9$/L (NR: 1.56-6.45 × $10^9$/L), and low hemoglobin level of 117 g/L (NR: 132-166 g/L).<br><br>The participant had an urgent care visit (once) and went to the emergency room (once). The participant was hospitalized on PPD (Day 166) for 3 days and discharged on PPD (Day 169).<br><br>On PPD (Day 166), the participant began experiencing neurological dysfunction (difficulty walking and disorientation). No other cause was reported, and a head CT scan showed no acute intracranial abnormality. However, per the participant, a head CT scan on PPD (Day 194) showed evidence of a stroke. The start date of the stroke was reported as when symptoms of neurological dysfunction started.<br><br>The participant therefore had severe COVID-19 illness per protocol criteria (ie, confirmed COVID-19 and hospitalization). |

| Demography | | | | |
|---|---|---|---|---|
| **Date of Birth** | **Age at Enrollment (Years)** | **Race** | **Ethnicity** | **Sex** |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| **Height** | **Weight** | **BMI** | **Date Collected (Study Day)** |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| **Investigator Text** | **MedDRA Preferred Term** | **Start Date** | **Disease Status** |
| PPD | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events |
|---|
| No Adverse Events |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |

| Case Details | | |
|---|---|---|
| Visit | >7 Days After Booster | Severe |
| COVID Illness Visit 1 | Yes | No |
| COVID Illness Visit 2 | Yes | No |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| **Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing** | **Prespecified Event** | **Symptoms (Prespecified and Others)** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 / PPD (14)/ PPD (13)/ PPD (18) | NO | | Nasal dryness |
| | YES | VOMITING | |
| | NO | | Decreased appetite |
| | YES | DIARRHEA | |
| | YES | CHILLS | |
| COVID Illness Visit 2 / PPD (168)/ PPD (165)/ PPD (171) | YES | VOMITING | |
| | NO | | Nasal discomfort |
| | YES | NEW OR INCREASED SORE THROAT | |
| | NO | | Fatigue |
| | YES | FEVER | |
| | NO | | Decreased appetite |
| | YES | DIARRHEA | |
| | YES | CHILLS | |

| Diagnosis of Potential COVID-19 Illness |
|---|
| No Diagnosis of Potential COVID-19 Illness |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| 1 | COVID Illness Visit 1 | PPD (14) | PPD (15) | SWABBED MATERIAL | POSITIVE |
| 2 | COVID Illness Visit 2 | PPD (168) | PPD (170) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory |
|---|
| No SARS-COV-2 Test - Local Laboratory |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (14) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 2 | PPD (168) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details |
|---|
| No Hospitalization Details |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry |
|---|
| No Laboratory Results - Clinical Chemistry |

| Laboratory Results - Hematology |
|---|
| No Laboratory Results - Hematology |

| Vital Signs - COVID-19 |
|---|
| No Vital Signs - COVID-19 |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging |
|---|
| No Imaging |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 60-year-old PPD with a BMI of PPD kg/m$^2$, received BNT162b2 on PPD (Day 1).<br><br>The participant had a pertinent medical history of PPD (in PPD), and PPD (since PPD).<br><br>The central laboratory SARS-CoV-2 NAAT and N-binding antibody results were negative at Visit 1.<br><br>On PPD (Day 14), the participant reported nasal dryness, vomiting, decreased appetite, diarrhea, and chills, with the first symptom starting on PPD, 12 days after receiving BNT162b2, and the last symptom resolved on PPD (Day 18).<br><br>The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on PPD (Day 15) was positive. No local laboratory SARS-CoV-2 NAAT was done.<br><br>On PPD (Day 168), the participant reported nasal discomfort, vomiting, decreased appetite, diarrhea, chills, fever, fatigue, and new or increased sore throat, with the first symptom starting on PPD, 164 days after receiving BNT162b2, and the last symptom resolved on PPD (Day 171).<br><br>The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on PPD (Day 170) was positive. No local laboratory SARS-CoV-2 NAAT was done.<br><br>The participant did not have any contact with nonstudy healthcare personnel (at COVID-19 illness visits 1 and 2). |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 30 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Present |
| | | | Past |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** |
| 1 | GASTR | Diarrhoea | PPD | PPD (1) | | PPD (26) | |
| 2 | GENRL | Fatigue | | PPD (1) | | PPD (26) | |
| 3 | NERV | Headache | | PPD (1) | | PPD (26) | |
| 4 | MUSC | Myalgia | | PPD (1) | | PPD (26) | |
| 5 | GASTR | Nausea | | PPD (4) | | PPD (26) | |
| 6 | GENRL | Pain | | PPD (1) | | PPD (26) | |
| 7 | GENRL | Pyrexia | | PPD (1) | | PPD (5) | |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Duration (Days)** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 26 | 2 | TC | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 2 | 26 | 2 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 3 | 26 | 2 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 4 | 26 | 2 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 5 | 23 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 4 | N |
| 6 | 26 | 2 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 7 | 5 | 1 | TC | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | POSITIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |

| Case Details | | |
|---|---|---|
| Visit | >7 Days After Booster | Severe |
| COVID Illness Visit 1 | No | No |
| COVID Illness Visit 3 | Yes | No |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| **Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing** | **Prespecified Event** | **Symptoms (Prespecified and Others)** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 / PPD (12)/ PPD (1)/ PPD (26) | NO | | Rhinorrhoea |
| | NO | | Nasal congestion |
| | YES | NEW OR INCREASED COUGH | |
| COVID Illness Visit 2 / PPD (103)/ PPD (101)/ PPD (108) | NO | | Pain |
| | NO | | Nasal congestion |
| | NO | | Headache |
| | NO | | Fatigue |
| | YES | FEVER | |
| | YES | CHILLS | |
| COVID Illness Visit 3 / PPD (156)/ PPD (152)/ ONGOING | NO | | Nasal congestion |
| | YES | NEW OR INCREASED SORE THROAT | |
| | NO | | Rhinorrhoea |
| | NO | | Fatigue |
| | YES | FEVER | |

| Diagnosis of Potential COVID-19 Illness |
|---|
| No Diagnosis of Potential COVID-19 Illness |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| 1 | COVID Illness Visit 1 | PPD (12) | PPD (12) | SWABBED MATERIAL | POSITIVE |
| 2 | COVID Illness Visit 2 | PPD (103) | PPD (103) | SWABBED MATERIAL | NEGATIVE |
| 3 | COVID Illness Visit 3 | PPD (156) | PPD (156) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory |
|---|
| No SARS-COV-2 Test - Local Laboratory |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (12) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |
| COVID Illness Visit 2 | PPD (103) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |
| COVID Illness Visit 3 | PPD (156) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | YES | 1 | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details |
|---|
| No Hospitalization Details |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry |
|---|
| No Laboratory Results - Clinical Chemistry |

| Laboratory Results - Hematology |
|---|
| No Laboratory Results - Hematology |

| Vital Signs - COVID-19 |
|---|
| No Vital Signs - COVID-19 |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging |
|---|
| No Imaging |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

**Narrative Comment**

Participant PPD, a 30-year-old PPD with a BMI of PPD kg/m$^2$, received BNT162b2 on PPD (Day 1).

The participant had a pertinent medical history of PPD (in PPD , PPD (in PPD ), and PPD (PP ; since PPD ).

The central laboratory SARS-CoV-2 NAAT result was positive at Visit 1. The central laboratory N-binding antibody result was negative at Visit 1.

On PPD (Day 12), the participant reported a new or increased cough, nasal congestion, and rhinorrhea, with the first symptom starting on PPD , on the same day of receiving BNT162b2, and the last symptom resolved on PPD (Day 26).

The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on PPD (Day 12) was positive. No local laboratory SARS-CoV-2 NAAT was done.

On PPD (Day 103), the participant reported chills, fever, fatigue, headache, nasal congestion, and pain, with the first symptom starting on PPD , 100 days after receiving BNT162b2, and the last symptom resolved on PPD (Day 108).

The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on PPD (Day 103) was negative. No local laboratory SARS-CoV-2 NAAT was done.

The participant did not have any contact with nonstudy healthcare personnel (at COVID-19 illness visits 1 and 2).

On PPD (Day 156), the participant reported fever, fatigue, new or increased sore throat, nasal congestion, and rhinorrhea, with the first symptom starting on PPD, 151 days after receiving BNT162b2, and at least 1 symptom was ongoing as of the last available report.

The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on PPD (Day 156) was positive. No local laboratory SARS-CoV-2 NAAT was done.

The participant had a telephone consultation (once) (at COVID-19 illness visit 3).

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 60 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Past |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** | **Duration (Days)** |
| 1 | CARD | Atrial fibrillation | PPD | PPD (150) | | PPD (151) | | 2 |
| 2 | INFEC | Cellulitis | | PPD (90) | | PPD (139) | | 50 |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 1 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: PPD | 1 | 150 | N |
| 2 | 1 | TC | Y | Resolved (PPD) | NOT RELATED/OTHER: PPD injury | 1 | 90 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Date of Collection (Study Day)** | **Specimen Type** | **Test Result** |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |

| Case Details | | |
|---|---|---|
| **Visit** | **>7 Days After Booster** | **Severe** |
| COVID Illness Visit 1 | Yes | Yes |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| **Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing** | **Prespecified Event** | **Symptoms (Prespecified and Others)** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 / PPD (178)/ PPD (176)/ ONGOING | YES | NEW OR INCREASED SORE THROAT | |
| | YES | NEW OR INCREASED SHORTNESS OF BREATH | |
| | YES | CHILLS | |
| | YES | NEW OR INCREASED COUGH | |

| Diagnosis of Potential COVID-19 Illness | | | | | |
|---|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Respiratory Illness Diagnosis** | **Date of Diagnosis (Study Day)** | **Toxicity Grade** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 | PPD (178) | CoVID 19 | PPD (177) | 2 | COVID-19 |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| 1 | COVID Illness Visit 1 | PPD (178) | PPD (178) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory | | | | |
|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type |
| 1 | COVID Illness Visit 1 | PPD (178) | PPD (177) | SWABBED MATERIAL |

| SARS-COV-2 Test - Local Laboratory | | | | |
|---|---|---|---|---|
| Lab Test Number | Specimen Collection Location | Test Result | Comments/Findings/Details | Trade Name |
| 1 | NASOPHARYNX | POSITIVE | | PPD |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (178) | OTHER | YES | | HOSPITAL |
| | | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | YES | 1 | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Hospitalization Category | Hospitalization Term | Admission Date (Study Day) | Discharge Date or Ongoing (Study Day) |
| COVID Illness Visit 1 | PPD (178) | HOSPITALIZATION STATUS | HOSPITAL | PPD (177) | PPD (181) |

| Respiratory Treatment | | | | | | |
|---|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Treatment Identifier | Prespecified Concomitant Nondrug Treatment | Treatment | Start Date (Study Day) | End Date or Ongoing (Study Day) |
| COVID Illness Visit 1 | PPD (178) | 1 | YES | Continuous Positive Airway Pressure (CPAP) | PPD (177) | ONGOING |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry | | | | | | | |
|---|---|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date of Test (Study Day) | Laboratory Test | Result | Units | Lower Limit Range | Upper Limit Range |
| COVID Illness Visit 1 | PPD (178) | PPD (177) | Alkaline Phosphatase | 1.37 | ukat/L | 0.63 | 2.1 |
| | | PPD (177) | Alanine Aminotransferase | 0.43342 | ukat/L | 0 | . |
| | | PPD (177) | Aspartate Aminotransferase | 0.63346 | ukat/L | 0.28339 | 0.98353 |
| | | PPD (177) | Bilirubin | 6.8 | umol/L | 3.4 | 22.2 |
| | | PPD (177) | Creatinine | 61.9 | umol/L | 61.9 | 132.6 |
| | | PPD (177) | C Reactive Protein | 6.8 | mg/L | 0 | 5 |
| | | PPD (177) | Urea Nitrogen | 3.93 | mmol/L | 3.21 | 7.14 |

**Laboratory Results - Hematology**

| Visit | Visit Date (Study Day) | Date of Test (Study Day) | Laboratory Test | Result | Units | Lower Limit Range | Upper Limit Range |
|---|---|---|---|---|---|---|---|
| COVID Illness Visit 1 | PPD (178) | PPD (177) | Basophils | UNCONVERTED | 10^9/L | 0 | 3 |
| | | PPD (177) | Eosinophils | UNCONVERTED | 10^9/L | 0 | 15 |
| | | PPD (177) | Hematocrit | 0.44 | L/L | 0.42 | 0.52 |
| | | PPD (177) | Hemoglobin | 146 | g/L | 140 | 180 |
| | | PPD (177) | Lymphocytes | UNCONVERTED | 10^9/L | 20.5 | 45.5 |
| | | PPD (177) | Monocytes | UNCONVERTED | 10^9/L | 2 | 15 |
| | | PPD (177) | Neutrophils | UNCONVERTED | 10^9/L | 43 | 85 |
| | | PPD (177) | Platelets | 196000 | 10^9/L | 130000 | 400000 |

**Vital Signs - COVID-19**

| Visit | Visit Date (Study Day) | Date Collected (Study Day) | Record Identifier | Systolic Blood Pressure | Diastolic Blood Pressure | Respiratory Rate | Heart Rate | Oxygen Saturation |
|---|---|---|---|---|---|---|---|---|
| COVID Illness Visit 1 | PPD (178) | PPD (177) | 1 | | | | | 75 % |
| | | PPD (178) | 2 | 153 mmHg | 77 mmHg | 22 breaths/min | 72 beats/min | 96 % |
| | | PPD (181) | 3 | | | | | 94 % |

**Oxygenation Parameters**

No Oxygenation Parameters

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging | | | | | |
|---|---|---|---|---|---|
| **Assessment Number** | **Visit** | **Visit Date (Study Day)** | **Date of Assessment** | **Location of Assessment** | **If Other, Specify** |
| 1 | COVID Illness Visit 1 | PPD (178) | PPD | CHEST | |

| Imaging | | | | |
|---|---|---|---|---|
| **Assessment Number** | **Type of Imaging Exam** | **If Other, Specify** | **Overall Assessment** | **If Abnormal, Specify Findings** |
| 1 | X-RAY | NA | ABNORMAL | Faint opacity at lower left lung zone. Atelectasis versus mild atypical pneumonia. |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| **Narrative Comment** |
|---|
| Participant PPD, a 60 -year-old PPD with a BMI of PPD kg/m$^2$, received BNT162b2 on PPD (Day 1).<br><br>The participant had a pertinent medical history of PPD (since PPD) and PPD (since PPD).<br><br>The central laboratory SARS-CoV-2 NAAT and N-binding antibody results were negative at Visit 1.<br><br>On PPD (Day 90), the participant went to the emergency department with a 1-day history of right knee pain. It was reported that the participant had a PPD injury to the same area about 6 weeks ago that required sutures. The participant had a mild infection and was treated with PPD. On PPD (Day 119), PPD noticed increased pain and swelling in PPD right leg, with some swelling spreading down PPD right calf. PPD denied fever, chills, or other complaints. On PPD (Day 120), PPD was admitted to the hospital and started on PPD. A computed tomography scan of the right lower extremity was consistent with severe cellulitis without abscess and a duplex ultrasound examination of the lower right extremity showed no deep vein thrombosis. The participant had elevated C-reactive protein levels of 9.2 mg/L and 13.2 mg/L (normal range: 0-5 mg/L) on PPD (Day 120). On an unknown date, the participant was discharged on PPD, which was later changed to PPD on PPD (Day 132). The cellulitis resolved on PPD (Day 139).<br><br>On PPD (Day 151), the participant presented to the emergency department with a 1-day history of right-sided chest pain along with shortness of breath. PPD shortness of breath worsened on exertion. No other symptoms were reported. The physical examination, including cardiac examination, was normal. On the same day (Day 151), a chest x-ray examination was normal, and an electrocardiogram showed atrial fibrillation at 67 beats/min. On PPD (Day 153), a transthoracic echocardiogram showed preserved ejection fraction with no clinically significant abnormalities and a cardiac catheterization showed minimal plaquing in the left anterior descending artery and circumflex arteries, with no clinically significant findings. The participant was transferred to a tertiary care center, where PPD spontaneously converted to a normal sinus rhythm and was treated with PPD in the hospital and was later transitioned to PPD as an outpatient. PPD was stable and discharged from the hospital on PPD (Day 154). |

On PPD (Day 177), the participant was diagnosed with severe COVID-19 and reported new or increased sore throat, new or increased shortness of breath, chills, and new or increased cough, with the first symptom starting on PPD, 175 days after receiving BNT162b2, and at least 1 symptom was ongoing as of the last available report.

The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on PPD (Day 177) was positive. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on PPD (Day 178) was positive.

The participant went to the emergency room (once).

On PPD (Day 177), the participant's oxygen saturation was 75% on room air and PPD was hospitalized and placed on continuous positive airway pressure (CPAP; since PPD). On the same day (Day 177), PPD C-reactive protein level was 6.8 mg/L (normal range: 0-5 mg/L) and a chest radiograph showed faint opacity at the lower left lung zone suggestive of atelectasis versus mild atypical pneumonia.

On PPD (Day 178), the participant had a heart rate of 72 beats/min, blood pressure of 153/77 mm Hg, respiratory rate of 22 breaths/min, and oxygen saturation of 96%.

On PPD (Day 181), the participant had an oxygen saturation of 94% and PPD was discharged from the hospital on CPAP.

The participant therefore had a severe COVID-19 illness per protocol criteria (ie, confirmed COVID-19, oxygen saturation ≤93% on room air, mechanical ventilation, and hospitalization).

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 40 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Past |
| | | | Present |
| | | | Past |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (127) | PPD |

| Adverse Events |
|---|
| No Adverse Events |

| Prohibited Concomitant Medications | | | | |
|---|---|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** | **End Date** | **Route** |
| PPD | | | | |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |
| Visit 2 | PPD (127) | PPD (127) | SWABBED MATERIAL | POSITIVE |
| Visit 2 | PPD (127) | PPD (127) | SERUM | POSITIVE |

| Case Details | | |
|---|---|---|
| Visit | >7 Days After Booster | Severe |
| COVID Illness Visit 1 | Yes | Yes |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| **Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing** | **Prespecified Event** | **Symptoms (Prespecified and Others)** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 / PPD (32)/ PPD (31)/ PPD (50) | NO | | Peripheral swelling |
| | NO | | Nasal congestion |
| | YES | NEW OR INCREASED SORE THROAT | |
| | YES | NEW OR INCREASED MUSCLE PAIN | |
| | YES | NEW OR INCREASED COUGH | |
| | NO | | Headache |

| Diagnosis of Potential COVID-19 Illness | | | | | |
|---|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Respiratory Illness Diagnosis** | **Date of Diagnosis (Study Day)** | **Toxicity Grade** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 | PPD (32) | COVID 19 | PPD (31) | 2 | COVID-19 |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| 1 | COVID Illness Visit 1 | PPD (32) | PPD (32) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory | | | | |
|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type |
| 1 | COVID Illness Visit 1 | PPD (32) | PPD (31) | SWABBED MATERIAL |

| SARS-COV-2 Test - Local Laboratory | | | | |
|---|---|---|---|---|
| Lab Test Number | Specimen Collection Location | Test Result | Comments/Findings/Details | Trade Name |
| 1 | NASOPHARYNX | POSITIVE | | PPD COVID-19 Test |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (32) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | YES | 1 | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details |
|---|
| No Hospitalization Details |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry | | | | | | | |
|---|---|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date of Test (Study Day) | Laboratory Test | Result | Units | Lower Limit Range | Upper Limit Range |
| COVID Illness Visit 1 | PPD (32) | PPD (31) | Alkaline Phosphatase | 1.72 | ukat/L | 0.83 | 2.27 |
| | | PPD (31) | Alanine Aminotransferase | 0.43342 | ukat/L | 0 | 0.8335 |
| | | PPD (31) | Aspartate Aminotransferase | 0.36674 | ukat/L | 0.45009 | 0.6668 |
| | | PPD (31) | Bilirubin | 5.1 | umol/L | 1.7 | 17.1 |
| | | PPD (31) | Creatinine | 83 | umol/L | 70.7 | 88.4 |
| | | PPD (31) | Urea Nitrogen | 3.21 | mmol/L | 2.5 | 7.14 |

| Laboratory Results - Hematology | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Date of Test (Study Day)** | **Laboratory Test** | **Result** | **Units** | **Lower Limit Range** | **Upper Limit Range** |
| COVID Illness Visit 1 | PPD (32) | PPD (31) | Basophils | 0.03 | 10^9/L | 0 | 0.1 |
| | | PPD (31) | Eosinophils | 0.1 | 10^9/L | 0 | 0.6 |
| | | PPD (31) | Hematocrit | 0.44 | L/L | 0.4 | 0.53 |
| | | PPD (31) | Hemoglobin | 147 | g/L | 140 | 180 |
| | | PPD (31) | Lymphocytes | 1.1 | 10^9/L | 0.8 | 3.8 |
| | | PPD (31) | Monocytes | 0.76 | 10^9/L | 0.2 | 0.8 |
| | | PPD (31) | Neutrophils | 3.85 | 10^9/L | 2.3 | 7.8 |
| | | PPD (31) | Platelets | 156 | 10^9/L | 170 | 425 |
| | | PPD (31) | Erythrocytes | 5.01 | 10^12/L | 4.5 | 6 |
| | | PPD (31) | Leukocytes | 5.9 | 10^9/L | 4.3 | 11.8 |

| Vital Signs - COVID-19 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Date Collected (Study Day)** | **Record Identifier** | **Systolic Blood Pressure** | **Diastolic Blood Pressure** | **Respiratory Rate** | **Heart Rate** | **Oxygen Saturation** |
| COVID Illness Visit 1 | PPD (32) | PPD (31) | 1 | 131 mmHg | 77 mmHg | 20 breaths/min | 106 beats/min | 91 % |
| | | PPD (33) | 2 | 124 mmHg | 80 mmHg | 20 breaths/min | 92 beats/min | 96 % |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| Assessment Number | Visit | Visit Date (Study Day) | Date of Assessment | Location of Assessment | If Other, Specify | Type of Imaging Exam | If Other, Specify | Overall Assessment | If Abnormal, Specify Findings |
| 1 | COVID Illness Visit 1 | PPD (32) | PPD | CHEST | | X-RAY | NA | NORMAL | |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 40-year-old PPD with a BMI of PPD kg/m$^2$, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 127).<br><br>The participant had a pertinent medical history of PPD (in PPD), PPD (since PPD), PPD (since PPD), and PPD (in PPD).<br><br>The central laboratory SARS-CoV-2 NAAT and N-binding antibody results were negative at Visit 1 and positive at Visit 2.<br><br>On PPD (Day 31), the participant was diagnosed with severe COVID-19 and reported peripheral swelling, nasal congestion, new or increased sore throat, new or increased muscle pain, new or increased cough, and headache, with the first symptom starting on PPD, 30 days after receiving placebo, and the last symptom resolved on PPD (Day 50).<br><br>The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on PPD (Day 31) was positive. The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on PPD (Day 32) was positive.<br><br>The participant went to the emergency room (once).<br><br>On PPD (Day 31), the participant had a heart rate of 106 beats/min, blood pressure of 131/77 mm Hg, respiratory rate of 20 breaths/min, and oxygen saturation of 91% on room air. On PPD (Day 31), a chest radiograph was normal. On PPD (Day 31), the platelet count was 156 × $10^9$/L (normal range: 170-425 × $10^9$/L).<br><br>On PPD (Day 33), the participant had a heart rate of 92 beats/min, blood pressure of 124/80 mm Hg, respiratory rate of 20 breaths/min, and oxygen saturation of 96% on room air. The participant received PPD on PPD (Day 33).<br><br>The participant therefore had a severe COVID-19 illness per protocol criteria (ie, confirmed COVID-19 and oxygen saturation ≤93% on room air). |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 40 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time |
| 1 | GENRL | Fatigue | PPD | PPD (2) | PPD | PPD (2) | PPD |
| 2 | NERV | Headache | | PPD (2) | PPD | PPD (2) | PPD |
| 3 | NERV | Lethargy | | PPD (2) | PPD | PPD (2) | PPD |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | Duration (Days) | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 1 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 2 | 1 | 1 | TC | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |
| 3 | 1 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 2 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |

| Case Details | | |
|---|---|---|
| Visit | >7 Days After Booster | Severe |
| COVID Illness Visit 2 | Yes | Yes |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| **Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing** | **Prespecified Event** | **Symptoms (Prespecified and Others)** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 / PPD (51)/ PPD (50)/ PPD (54) | NO | | Rhinorrhoea |
| | YES | NEW OR INCREASED SORE THROAT | |
| COVID Illness Visit 2 / PPD (177)/ PPD (176)/ PPD (184) | NO | | Rhinorrhoea |
| | NO | | Nasal congestion |
| | YES | NEW OR INCREASED SORE THROAT | |
| | NO | | Pain |
| | YES | NEW OR INCREASED MUSCLE PAIN | |
| | YES | NEW OR INCREASED COUGH | |
| | YES | NEW OR INCREASED SHORTNESS OF BREATH | |
| | YES | CHILLS | |

| Diagnosis of Potential COVID-19 Illness | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Respiratory Illness Diagnosis | Date of Diagnosis (Study Day) | Toxicity Grade | MedDRA Preferred Term |
| COVID Illness Visit 2 | PPD (177) | COVID 19 | PPD (177) | 1 | COVID-19 |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| 1 | COVID Illness Visit 1 | PPD (51) | PPD (51) | SWABBED MATERIAL | NEGATIVE |
| 2 | COVID Illness Visit 2 | PPD (177) | PPD (177) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory | | | | |
|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type |
| 1 | COVID Illness Visit 2 | PPD (177) | PPD (177) | SWABBED MATERIAL |

| SARS-COV-2 Test - Local Laboratory | | | | |
|---|---|---|---|---|
| Lab Test Number | Specimen Collection Location | Test Result | Comments/Findings/Details | Trade Name |
| 1 | NASOPHARYNX | POSITIVE | | PPD SARS-COV-2 TEST |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (51) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |
| COVID Illness Visit 2 | PPD (177) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | YES | 1 | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details |
|---|
| No Hospitalization Details |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry |
|---|
| No Laboratory Results - Clinical Chemistry |

| Laboratory Results - Hematology |
|---|
| No Laboratory Results - Hematology |

**Vital Signs - COVID-19**

| Visit | Visit Date (Study Day) | Date Collected (Study Day) | Record Identifier | Systolic Blood Pressure | Diastolic Blood Pressure | Respiratory Rate | Heart Rate | Oxygen Saturation |
|---|---|---|---|---|---|---|---|---|
| COVID Illness Visit 2 | PPD (177) | PPD (177) | 1 | 129 mmHg | 83 mmHg | 20 breaths/min | 100 beats/min | 92 % |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging |
|---|
| No Imaging |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 40-year-old PPD with a BMI of PPD kg/m$^2$, received BNT162b2 on PPD (Day 1).<br><br>The participant had a pertinent medical history of PPD (since PPD) and PPD (since PPD).<br><br>The central laboratory SARS-CoV-2 NAAT and N-binding antibody results were negative at Visit 1.<br><br>On PPD (Day 177), the participant was diagnosed with severe COVID-19 and reported rhinorrhea, nasal congestion, new or increased sore throat, pain, new or increased muscle pain, new or increased cough, new or increased shortness of breath, and chills, with the first symptom starting on PPD, 175 days after receiving BNT162b2, and the last symptom resolved on PPD (Day 184).<br><br>The central laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on PPD (Day 177) was positive. The local laboratory SARS-CoV-2 NAAT result at the time of the COVID-19 illness on PPD (Day 177) was positive.<br><br>The participant went to the emergency room (once).<br><br>On PPD (Day 177), the participant had a heart rate of 100 beats/min, blood pressure of 129/83 mm Hg, respiratory rate of 20 breaths/min, and oxygen saturation of 92% on room air.<br><br>The participant therefore had a severe COVID-19 illness per protocol criteria (ie, confirmed COVID-19 and oxygen saturation ≤93% on room air). |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 30 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: PPD; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD; Date of Last Dose: PPD

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Past |
| | | | Past |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (128) | PPD |

| Adverse Events |
|---|
| No Adverse Events |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Date of Collection (Study Day)** | **Specimen Type** | **Test Result** |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |
| Visit 2 | PPD (128) | PPD (128) | SWABBED MATERIAL | NEGATIVE |
| Visit 2 | PPD (128) | PPD (128) | SERUM | POSITIVE |

| Case Details | | |
|---|---|---|
| **Visit** | **>7 Days After Booster** | **Severe** |
| COVID Illness Visit 1 | Yes | Yes |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| **Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing** | **Prespecified Event** | **Symptoms (Prespecified and Others)** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 / PPD (22)/ PPD (21)/ PPD (29) | NO | | Secretion discharge |
| | NO | | Nausea |
| | NO | | Nasal congestion |
| | YES | NEW OR INCREASED SORE THROAT | |
| | YES | NEW OR INCREASED MUSCLE PAIN | |
| | NO | | Headache |

| Diagnosis of Potential COVID-19 Illness | | | | | |
|---|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Respiratory Illness Diagnosis** | **Date of Diagnosis (Study Day)** | **Toxicity Grade** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 | PPD (22) | sinusitis | PPD (22) | 1 | Sinusitis |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| 1 | COVID Illness Visit 1 | PPD (22) | PPD (22) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory |
|---|
| No SARS-COV-2 Test - Local Laboratory |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (22) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | YES | 1 | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details |
|---|
| No Hospitalization Details |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry |
|---|
| No Laboratory Results - Clinical Chemistry |

| Laboratory Results - Hematology |
|---|
| No Laboratory Results - Hematology |

| Vital Signs - COVID-19 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date Collected (Study Day) | Record Identifier | Systolic Blood Pressure | Diastolic Blood Pressure | Respiratory Rate | Heart Rate | Oxygen Saturation |
| COVID Illness Visit 1 | PPD (22) | PPD (22) | 1 | 130 mmHg | 86 mmHg | 18 breaths/min | 99 beats/min | 93 % |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging |
|---|
| No Imaging |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |

Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): Placebo => BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD
==========

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 30-year-old PPD with a BMI of PPD kg/m$^2$, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 128).<br><br>The participant had a pertinent medical history of PPD (since PPD), PPD (PPD since PPD), PPD (since PPD), PPD (since PPD), PPD (since PPD), PPD (since PPD), PPD (PPD, since PPD), PPD (since PPD), PPD (since PPD), PPD (since PPD), and PPD PPD (in PPD).<br><br>The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody results were negative at Visit 1 and positive at Visit 2.<br><br>On PPD (Day 22), the participant was diagnosed with severe sinusitis and reported secretion discharge, nausea, nasal congestion, new or increased sore throat, new or increased muscle pain, and headache, with the first symptom starting on PPD, 20 days after receiving placebo, and the last symptom resolved on PPD (Day 29).<br><br>The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on PPD (Day 22) was positive. No local laboratory SARS-CoV-2 NAAT was done.<br><br>The participant went to the emergency room (once).<br><br>On PPD (Day 22), the participant had a heart rate of 99 beats/min, blood pressure of 130/86 mm Hg, respiratory rate of 18 breaths/min, and oxygen saturation of 93% on room air.<br><br>The participant therefore had a severe COVID-19 illness per protocol criteria (ie, confirmed COVID-19 and oxygen saturation ≤93% on room air). |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | ≤24 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History |
|---|
| No Medical History |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events |
|---|
| No Adverse Events |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |

| Case Details | | |
|---|---|---|
| **Visit** | **>7 Days After Booster** | **Severe** |
| COVID Illness Visit 1 | Yes | Yes |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| **Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing** | **Prespecified Event** | **Symptoms (Prespecified and Others)** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 / PPD (176)/ PPD (171)/ PPD (183) | NO | | Rhinitis |
| | NO | | Nasal congestion |
| | YES | NEW OR INCREASED COUGH | |
| | NO | | Headache |
| | NO | | Fatigue |

| Diagnosis of Potential COVID-19 Illness |
|---|
| No Diagnosis of Potential COVID-19 Illness |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| 1 | COVID Illness Visit 1 | PPD (176) | PPD (176) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory |
|---|
| No SARS-COV-2 Test - Local Laboratory |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (176) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details |
|---|
| No Hospitalization Details |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry |
|---|
| No Laboratory Results - Clinical Chemistry |

| Laboratory Results - Hematology |
|---|
| No Laboratory Results - Hematology |

| Vital Signs - COVID-19 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date Collected (Study Day) | Record Identifier | Systolic Blood Pressure | Diastolic Blood Pressure | Respiratory Rate | Heart Rate | Oxygen Saturation |
| COVID Illness Visit 1 | PPD (176) | PPD (176) | 1 | 118 mmHg | 52 mmHg | 12 breaths/min | 82 beats/min | 97 % |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging |
|---|
| No Imaging |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a ≤24-year-old PPD with a BMI of PPD kg/m$^2$, received BNT162b2 on PPD (Day 1).<br><br>The participant had no medical history reported.<br><br>The central laboratory SARS-CoV-2 NAAT and N-binding antibody results were negative at Visit 1.<br><br>On PPD (Day 176), the participant reported rhinitis, nasal congestion, new or increased cough, headache, and fatigue, with the first symptom starting on PPD, 170 days after receiving BNT162b2, and the last symptom resolved on PPD (Day 183).<br><br>The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on PPD (Day 176) was positive. No local laboratory SARS-CoV-2 NAAT was done.<br><br>The participant did not have any contact with nonstudy healthcare personnel.<br><br>On PPD (Day 176), the participant had a heart rate of 82 beats/min, blood pressure of 118/52 mm Hg, respiratory rate of 12 breaths/min, and oxygen saturation of 97% on room air.<br><br>The participant therefore had a severe COVID-19 illness per protocol criteria (ie, confirmed COVID-19 and diastolic blood pressure <60 mm Hg). |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 40 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Past |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (119) | PPD |

| Adverse Events |
|---|
| No Adverse Events |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Date of Collection (Study Day)** | **Specimen Type** | **Test Result** |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |
| Visit 2 | PPD (119) | PPD (119) | SWABBED MATERIAL | NEGATIVE |
| Visit 2 | PPD (119) | PPD (119) | SERUM | POSITIVE |

| Case Details | | |
|---|---|---|
| **Visit** | **>7 Days After Booster** | **Severe** |
| COVID Illness Visit 1 | Yes | Yes |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| **Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing** | **Prespecified Event** | **Symptoms (Prespecified and Others)** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 / PPD (84)/ PPD (78)/ PPD (113) | NO | | Nasal obstruction |
| | YES | NEW OR INCREASED MUSCLE PAIN | |
| | YES | NEW LOSS OF TASTE OR SMELL | |
| | YES | FEVER | |

| Diagnosis of Potential COVID-19 Illness |
|---|
| No Diagnosis of Potential COVID-19 Illness |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| 1 | COVID Illness Visit 1 | PPD (84) | PPD (84) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory |
|---|
| No SARS-COV-2 Test - Local Laboratory |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (84) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | YES | 1 | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details |
|---|
| No Hospitalization Details |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry |
|---|
| No Laboratory Results - Clinical Chemistry |

| Laboratory Results - Hematology |
|---|
| No Laboratory Results - Hematology |

| Vital Signs - COVID-19 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date Collected (Study Day) | Record Identifier | Systolic Blood Pressure | Diastolic Blood Pressure | Respiratory Rate | Heart Rate | Oxygen Saturation |
| COVID Illness Visit 1 | PPD (84) | PPD (84) | 1 | 98 mmHg | 72 mmHg | 16 breaths/min | 90 beats/min | 90 % |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging |
|---|
| No Imaging |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |

| Participant Summary | | | |
|---|---|---|---|
| **Status** | **Study Phase** | **Withdrawal/Completion Date** | **Reason for Withdrawal** |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 40-year-old PPD with a BMI of PPD kg/m$^2$, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 119).<br><br>The participant had no pertinent medical history.<br><br>The central laboratory SARS-CoV-2 NAAT results were negative at Visit 1 and Visit 2. The central laboratory N-binding antibody results were negative at Visit 1 and positive at Visit 2.<br><br>On PPD (Day 84), the participant reported fever, new loss of taste or smell, new or increased muscle pain, and nasal obstruction, with the first symptom starting on PPD, 77 days after receiving placebo, and the last symptom resolved on PPD (Day 113).<br><br>The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on PPD (Day 84) was positive. No local laboratory SARS-CoV-2 NAAT was done.<br><br>The participant went to the emergency room (once).<br><br>On PPD (Day 84), the participant had a heart rate of 90 beats/min, blood pressure of 98/72 mm Hg, respiratory rate of 16 breaths/min, and oxygen saturation of 90% on room air.<br><br>The participant therefore had a severe COVID-19 illness per protocol criteria (ie, confirmed COVID-19 and oxygen saturation ≤93% on room air). |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | ≤24 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time |
| 1 | GENRL | Injection site pain | PPD | PPD (1) | PPD | PPD (2) | |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| AE Number | Duration (Days) | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
| 1 | 2 | 1 | N | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| Investigator Text | WHO Drug Preferred Term | Start Date |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |

| Case Details | | |
|---|---|---|
| Visit | >7 Days After Booster | Severe |
| COVID Illness Visit 1 | Yes | Yes |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing | Prespecified Event | Symptoms (Prespecified and Others) | MedDRA Preferred Term |
| COVID Illness Visit 1 / PPD (193)/ PPD (190)/ PPD (204) | YES | NEW OR INCREASED COUGH | |
| | YES | DIARRHEA | |

| Diagnosis of Potential COVID-19 Illness |
|---|
| No Diagnosis of Potential COVID-19 Illness |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| 1 | COVID Illness Visit 1 | PPD (193) | PPD (193) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory |
|---|
| No SARS-COV-2 Test - Local Laboratory |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (193) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | YES | 1 | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details |
|---|
| No Hospitalization Details |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry |
|---|
| No Laboratory Results - Clinical Chemistry |

| Laboratory Results - Hematology |
|---|
| No Laboratory Results - Hematology |

| Vital Signs - COVID-19 | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Date Collected (Study Day)** | **Record Identifier** | **Systolic Blood Pressure** | **Diastolic Blood Pressure** | **Respiratory Rate** | **Heart Rate** | **Oxygen Saturation** |
| COVID Illness Visit 1 | PPD (193) | PPD (193) | 1 | 98 mmHg | 50 mmHg | 16 breaths/min | 57 beats/min | 99 % |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging |
|---|
| No Imaging |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a ≤24-year-old PPD with a BMI of PPD kg/m$^2$, received BNT162b2 on PPD (Day 1).<br><br>The participant had a persistent medical history of PPD (since PPD).<br><br>The central laboratory SARS-CoV-2 NAAT and N-binding antibody results were negative at Visit 1.<br><br>On PPD (Day 193), the participant reported new or increased cough and diarrhea, with the first symptom starting on PPD, 189 days after receiving BNT162b2, and the last symptom resolved on PPD (Day 204).<br><br>The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on PPD (Day 193) was positive. No local laboratory SARS-CoV-2 NAAT was done.<br><br>The participant went to the emergency room (once).<br><br>On PPD (Day 193), the participant had a heart rate of 57 beats/min, blood pressure of 98/50 mm Hg, respiratory rate of 16 breaths/min, and oxygen saturation of 99% on room air.<br><br>The participant therefore had a severe COVID-19 illness per protocol criteria (ie, confirmed COVID-19 and diastolic blood pressure <60 mm Hg). |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 40 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History | | | |
|---|---|---|---|
| Investigator Text | MedDRA Preferred Term | Start Date | Disease Status |
| PPD | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |
| | | | Present |

| Study Vaccination(s) | | | |
|---|---|---|---|
| **Vaccination Number** | **Vaccine** | **Vaccination Date (Study Day)** | **Time of Vaccination** |
| 1 | Placebo | PPD (1) | PPD |
| 2 | BNT162b2 | PPD (95) | PPD |

| Adverse Events | | | | | | | |
|---|---|---|---|---|---|---|---|
| **AE Number** | **MedDRA SOC** | **MedDRA Preferred Term** | **Investigator Text** | **Start Date (Study Day)** | **Start Time** | **Stop Date (Study Day)** | **Stop Time** |
| 1 | GENRL | Injection site pain | PPD | PPD (95) | PPD | PPD (95) | |

| Adverse Events | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| **AE Number** | **Duration (Days)** | **Toxicity Grade** | **Action to Participant** | **SAE** | **AE Still Present?** | **AE Related To:** | **Prior Vaccination Number** | **Relative Day From Prior Vaccination** | **Narrative Event** |
| 1 | 1 | 2 | TC | N | Resolved (PPD) | Study Treatment | 2 | 1 | N |

| Prohibited Concomitant Medications |
|---|
| No Prohibited Concomitant Medications |

| Nonstudy Vaccines | | |
|---|---|---|
| **Investigator Text** | **WHO Drug Preferred Term** | **Start Date** |
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Date of Collection (Study Day)** | **Specimen Type** | **Test Result** |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |
| Visit 2 | PPD (95) | PPD (95) | SWABBED MATERIAL | NEGATIVE |
| Visit 2 | PPD (95) | PPD (95) | SERUM | NEGATIVE |

| Case Details | | |
|---|---|---|
| **Visit** | **>7 Days After Booster** | **Severe** |
| COVID Illness Visit 1 | Yes | Yes |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| **Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing** | **Prespecified Event** | **Symptoms (Prespecified and Others)** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 / PPD (182)/ PPD (178)/ PPD (186) | NO | | Rhinorrhoea |
| | NO | | Nasal congestion |
| | YES | NEW OR INCREASED SORE THROAT | |

| Diagnosis of Potential COVID-19 Illness |
|---|
| No Diagnosis of Potential COVID-19 Illness |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| **Lab Test Number** | **Visit** | **Visit Date (Study Day)** | **Date of Collection (Study Day)** | **Specimen Type** | **Test Result** |
| 1 | COVID Illness Visit 1 | PPD (182) | PPD (182) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory |
|---|
| No SARS-COV-2 Test - Local Laboratory |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (182) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details |
|---|
| No Hospitalization Details |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry |
|---|
| No Laboratory Results - Clinical Chemistry |

| Laboratory Results - Hematology |
|---|
| No Laboratory Results - Hematology |

**Vital Signs - COVID-19**

| Visit | Visit Date (Study Day) | Date Collected (Study Day) | Record Identifier | Systolic Blood Pressure | Diastolic Blood Pressure | Respiratory Rate | Heart Rate | Oxygen Saturation |
|---|---|---|---|---|---|---|---|---|
| COVID Illness Visit 1 | PPD (182) | PPD (182) | 1 | 89 mmHg | 62 mmHg | 15 breaths/min | 83 beats/min | |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

| Imaging |
|---|
| No Imaging |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| Completed | OPEN LABEL TREATMENT | PPD | |
| | FOLLOW-UP | | |

| **Narrative Comment** |
|---|
| Participant PPD, a 40-year-old PPD with a BMI of PPD kg/m$^2$, received placebo on PPD (Day 1) and BNT162b2 on PPD (Day 95).<br><br>The participant had a persistent medical history of PPD (since PPD .<br><br>The central laboratory SARS-CoV-2 NAAT and N-binding antibody results were negative at Visit 1 and Visit 2.<br><br>On PPD (Day 182), the participant reported rhinorrhea, nasal congestion, and new or increased sore throat, with the first symptom starting on PPD, 83 days after receiving BNT162b2, and the last symptom resolved on PPD (Day 186).<br><br>The central laboratory SARS-CoV-2 NAAT result at the time of the potential COVID-19 illness visit on PPD (Day 182) was positive. No local laboratory SARS-CoV-2 NAAT was done.<br><br>The participant did not have any contact with nonstudy healthcare personnel.<br><br>On PPD (Day 182), the participant had a heart rate of 83 beats/min, blood pressure of 89/62 mm Hg, and respiratory rate of 15 breaths/min.<br><br>The participant therefore had a severe COVID-19 illness per protocol criteria (ie, confirmed COVID-19 and systolic blood pressure <90 mm Hg). |

| Demography | | | | |
|---|---|---|---|---|
| Date of Birth | Age at Enrollment (Years) | Race | Ethnicity | Sex |
| PPD | 40 | PPD | | |

| Vital Signs - Baseline | | | |
|---|---|---|---|
| Height | Weight | BMI | Date Collected (Study Day) |
| PPD cm | PPD kg | PPD kg/m2 | PPD (1) |

| Medical History |
|---|
| No Medical History |

| Study Vaccination(s) | | | |
|---|---|---|---|
| Vaccination Number | Vaccine | Vaccination Date (Study Day) | Time of Vaccination |
| 1 | BNT162b2 | PPD (1) | PPD |

**Adverse Events**

| AE Number | MedDRA SOC | MedDRA Preferred Term | Investigator Text | Start Date (Study Day) | Start Time | Stop Date (Study Day) | Stop Time |
|---|---|---|---|---|---|---|---|
| 1 | GENRL | Chills | PPD | PPD (1) | PPD | PPD (2) | |
| 2 | GENRL | Injection site pain | | PPD (1) | PPD | PPD (2) | |

**Adverse Events**

| AE Number | Duration (Days) | Toxicity Grade | Action to Participant | SAE | AE Still Present? | AE Related To: | Prior Vaccination Number | Relative Day From Prior Vaccination | Narrative Event |
|---|---|---|---|---|---|---|---|---|---|
| 1 | 2 | 1 | TC | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |
| 2 | 2 | 1 | TC | N | Resolved (PPD) | Study Treatment | 1 | 1 | N |

**Prohibited Concomitant Medications**

| |
|---|
| No Prohibited Concomitant Medications |

**Nonstudy Vaccines**

| Investigator Text | WHO Drug Preferred Term | Start Date |
|---|---|---|
| PPD | | |

| SARS-COV-2 Baseline Tests - Central Laboratory | | | | |
|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| Visit 1 | PPD (1) | PPD (1) | SWABBED MATERIAL | NEGATIVE |
| Visit 1 | PPD (1) | PPD (1) | SERUM | NEGATIVE |

| Case Details | | |
|---|---|---|
| Visit | >7 Days After Booster | Severe |
| COVID Illness Visit 1 | Yes | No |
| COVID Illness Visit 2 | Yes | No |

| Signs and Symptoms of Potential COVID-19 | | | |
|---|---|---|---|
| **Visit/ Visit Date or Date of Assessment (Study Day)/ Date First Symptom Started (Study Day)/ Date Last Symptom Resolved (Study Day) or Ongoing** | **Prespecified Event** | **Symptoms (Prespecified and Others)** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 / PPD (183)/ PPD (180)/ PPD (184) | NO | | Rhinorrhoea |
| | YES | NEW OR INCREASED SORE THROAT | |
| | YES | NEW OR INCREASED MUSCLE PAIN | |
| COVID Illness Visit 2 / PPD (192)/ PPD (189)/ PPD (194) | NO | | Rhinorrhoea |
| | YES | NEW OR INCREASED SORE THROAT | |

| Diagnosis of Potential COVID-19 Illness | | | | | |
|---|---|---|---|---|---|
| **Visit** | **Visit Date (Study Day)** | **Respiratory Illness Diagnosis** | **Date of Diagnosis (Study Day)** | **Toxicity Grade** | **MedDRA Preferred Term** |
| COVID Illness Visit 1 | PPD (183) | flu syndrome | PPD (180) | 1 | Influenza |
| COVID Illness Visit 2 | PPD (192) | COVID-19 | PPD (183) | 1 | COVID-19 |

| SARS-COV-2 Test - Central Laboratory | | | | | |
|---|---|---|---|---|---|
| Lab Test Number | Visit | Visit Date (Study Day) | Date of Collection (Study Day) | Specimen Type | Test Result |
| 1 | COVID Illness Visit 1 | PPD (183) | PPD (183) | SWABBED MATERIAL | POSITIVE |
| 2 | COVID Illness Visit 2 | PPD (192) | PPD (192) | SWABBED MATERIAL | POSITIVE |

| SARS-COV-2 Test - Local Laboratory |
|---|
| No SARS-COV-2 Test - Local Laboratory |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 1 | PPD (183) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Health Care Utilization | | | | | |
|---|---|---|---|---|---|
| Visit | Visit Date (Study Day) | Physician, Healthcare Professional, or Other Type of Practitioner (Specify) | Occurrence of Visits/Contacts | Number of Visits or Contacts | Other Type of Practitioner (Specify) |
| COVID Illness Visit 2 | PPD (192) | OTHER | NO | | NA |
| | | SPECIALIST | NO | | NA |
| | | EMERGENCY ROOM | NO | | NA |
| | | PRIMARY CARE PHYSICIAN | NO | | NA |
| | | URGENT CARE | NO | | NA |
| | | TELEPHONE CONSULTATION | NO | | NA |
| | | OTHER | NO | | NA |

| Hospitalization Details |
|---|
| No Hospitalization Details |

| Respiratory Treatment |
|---|
| No Respiratory Treatment |

| Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |
|---|
| No Diagnosis of Significant Acute Renal, Hepatic or Neurological Dysfunction |

| Laboratory Results - Clinical Chemistry |
|---|
| No Laboratory Results - Clinical Chemistry |

| Laboratory Results - Hematology |
|---|
| No Laboratory Results - Hematology |

| Vital Signs - COVID-19 |
|---|
| No Vital Signs - COVID-19 |

| Oxygenation Parameters |
|---|
| No Oxygenation Parameters |

| Concomitant Medications - Vasopressors |
|---|
| No Concomitant Medications - Vasopressors |

Reason(s) for Narrative: COVID-19 Case (Severe and/or Multiple)
Participant: PPD ; Country: PPD
Vaccine Group (as Administered): BNT162b2 (30 µg)
Date of First Dose: PPD ; Date of Last Dose: PPD

| Imaging |
|---|
| No Imaging |

| Participant Summary | | | |
|---|---|---|---|
| Status | Study Phase | Withdrawal/Completion Date | Reason for Withdrawal |
| Completed | SCREENING | PPD | |
| Completed | BOOSTER VACCINATION | PPD | |
| Completed | TREATMENT UNBLINDED | PPD | |
| | OPEN LABEL TREATMENT | | |
| | FOLLOW-UP | | |

| Narrative Comment |
|---|
| Participant PPD, a 40-year-old PPD with a BMI of PPD kg/m$^2$, received BNT162b2 on PPD (Day 1).<br><br>The participant had no reported medical history.<br><br>The central laboratory SARS-CoV-2 NAAT and N-binding antibody results were negative at Visit 1.<br><br>On PPD (Day 183), the participant had a COVID-19 illness visit because of rhinorrhea, new or increased sore throat, and new or increased muscle pain, with the first symptom starting on PPD, 179 days after receiving BNT162b2. PPD was diagnosed with flu syndrome. The last symptom resolved on PPD (Day 184).<br><br>On PPD (Day 192), the participant had a COVID-19 illness visit because of a new or increased sore throat and rhinorrhea, with the first symptom starting on PPD, 188 days after receiving BNT162b2. The last symptom resolved on PPD (Day 194).<br><br>The central laboratory SARS-CoV-2 NAAT results at the time of the COVID-19 illness on PPD (Day 183) and PPD (Day 192) were positive. No local laboratory SARS-CoV-2 NAAT was done.<br><br>The participant did not have any contact with nonstudy healthcare personnel (at COVID-19 illness visits 1 and 2). |